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In the Supreme Court of the United States

OCTOBER TERM, 1949

No. 568

OSCAR R. EWING, FEDERAL SECURITY ADMINISTRATOR, ET AL., APPELLANTS

v.

MYTINGER & CASSELBERRY, INC., A CALIFORNIA CORPORATION

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR THE APPELLANTS

OPINION BELOW

The district court delivered no written opinion, but made findings of fact and conclusions of law which are reported in 87 F. Supp. 650 (R. 756-771).

JURISDICTION

The final decree of permanent injunction was entered by the United States District Court for the District of Columbia, specially constituted

under 28 U.S.C. 2282 and 2284, on December 14, 1949 (R. 771). The appeal was allowed on January 9, 1950 (R. 773), and this Court noted probable jurisdiction on February 20, 1950 (R. 1565). This Court has jurisdiction under 28 U.S.C. 1253 and 2101(a) to review the judgment and decree by direct appeal.

The judgment and decree (R. 771) permanently enjoin the enforcement, operation, and execution of a part of Section 304(a) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U.S.C. 334(a), on the ground that it violates the due process clause of the Fifth Amendment to the Constitution of the United States.

QUESTIONS PRESENTED

Section 304(a) of the Federal Food, Drug, and Cosmetic Act permits multiple libel suits to be filed against a misbranded drug "when the Administrator has probable cause to believe from facts found, without hearing, * * * that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer." The questions presented by this appeal are:

1. Whether this provision violates the due process clause of the Fifth Amendment because it permits the Administrator to find "probable cause" without holding a hearing.

2. Whether the District Court had jurisdiction to review the Administrator's determination of probable cause.

3. Whether the District Court had jurisdiction to decide whether the labeling of appellee's product was misleading.

4. Whether, if the District Court had jurisdiction to determine the issue, the administrative finding of probable cause rested upon a rational basis.

5. Whether, if the District Court had jurisdiction to determine the issue, appellee's labeling was misleading.

6. Whether the District Court committed procedural errors requiring reversal:

(a) in unreasonably curtailing the cross-examination of appellee's witnesses;

(b) in the admission and exclusion of evidence;

(c) in pre-trial rulings that appellee could probe appellants' mental processes and require the production of agency files for its examination without showing "good cause"; and

(d) in ruling that appellee's "good faith" was a material issue.

STATUTE INVOLVED

Section 304 of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U.S.C. 334, provides in pertinent part as follows:

(a) Any article of * * * drug * * * that is * * * misbranded when introduced into

or while in interstate commerce * * * shall be liable to be proceeded against * * * on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. * * *

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involv-

ing the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States Attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

STATEMENT

Mytinger & Casselberry, Inc., appellee herein, is the exclusive national distributor of "Nutralite Food Supplement", an encapsulated concentrate of alfalfa, watercress, parsley, and synthetic vitamins combined in a package with mineral tablets

(Pl. Ex. 8, R. 725, 740, 55).¹ The drug² is not marketed through customary retail channels, but is sold by salesmen who directly solicit consumer contracts (R. 725, 56, 213-214, 315). These salesmen approach prospective customers with a booklet entitled "How to Get Well and Stay Well", which discusses the relation between vitamins, nutrition, and disease. As part of the sales promotion program, this booklet is left with the prospective purchaser on loan for perusal at his leisure. The salesman calls for the booklet a few days later and undertakes to obtain a contract for delivery of a year's supply of Nutrilite (one box each month) costing approximately \$200 a year payable in monthly installments. (R. 315.)

The booklet has been through several revisions, each precipitated by regulatory action on the part of the Food and Drug Administration. An early version (Deft. Ex. 7, R. 1104, 298), in use until May 1948, was the basis for an indictment returned in the Southern District of California charging Lee S. Mytinger and William S. Casselberry, as partners, with deliberately misrepresenting the therapeutic value of Nutrilite, in violation of the Federal Food, Drug, and Cosmetic

¹ Plaintiff's Ex. 8, a box and label of Nutrilite, is on file with the Clerk of this Court.

² Although under the statutory definition appellee's product is a drug (Section 201(g), 21 U.S.C. 321(g)), appellee prefers to characterize it as a food. The difference is immaterial, inasmuch as the applicable statutory provisions are identical. Sections 403(a), 502(a), 304, 21 U.S.C. 343(a), 352(a) and 334.

Act.³ (R. 729, 751). In this version the booklet represented, without qualification, that Nutrilite is an effective therapeutic agent in "almost every case" and is a cure of "common ailments" (R. 1155), which were specifically listed⁴ as "low blood pressure, ulcers, mental depression, pyorrhea, muscular twitching, rickets, worry over small things, tonsilitis, hay fever, sensitiveness to noise, underweight, easily tired, gas in stomach, cuts heal slowly, faulty vision, headache, constipation, anemia, boils, lack of ambition, certain bone conditions, nervousness, nosebleed, insomnia (sleeplessness), allergies, asthma, restlessness, bad skin color, poor appetite, biliousness, neuritis, night blindness, migraine, high blood pressure, sinus trouble, lack of concentration, dental caries, irregular heartbeat, flabby tissues, hysterical tendency, eczema, overweight, faulty memory, colitis, craving for sour foods, arthritis (rheumatism), neuralgia, deafness, subject to colds" (R. 1155-1156). At another point (R. 1127), it implied that "cancer, diabetes, heart trouble, high blood pressure, constipation, tuberculosis, arthritis, neuritis" and numerous other

³ This case had not been tried. An injunction suit was also brought against appellee in the Southern District of California on September 22, 1949. Trial of that proceeding has been put off by reason of the pendency of the instant case; in any event, unless the findings in the instant case are set aside by this Court, appellee will assert that they are *res judicata* and dispositive of the injunction proceeding.

⁴ The list was omitted in subsequent revisions; for a time a similar list appeared on a card shown to prospective purchasers (Def. Ex. 3, R. 1058C, 198).

diseases would respond to Nutrilite treatment.

As a result of governmental action (Pl. Ex. 9, R. 1018, 56, 35, 726-729, 750-751), the partners consulted an attorney who advised that the booklet be revised to eliminate the names of all diseases, and the use instead of descriptions of symptoms manifested by persons who had sought relief through Nutrilite (R. 35, 207-208). The 58-page edition of "How to Get Well and Stay Well", one of those involved in the present case, was the result of such revision (Pl. Ex. 1, R. 783-843, 207-208).

The change in technique is readily apparent from a comparison of the two booklets (Deft. Ex. 7, R. 1104-1162D, 298, Pl. Ex. 1, R. 783-843).⁵ Pages 37-58 do not make direct curative claims, but include a number of case histories explaining how persons have obtained relief and freedom from various ailments and symptoms of disease listed in the following paragraph (R. 822-843).

The Administrative Determinations and the Libels. On September 28, 1948, appellant Charles W. Crawford, Associate Commissioner of Food and Drugs, recommended that a seizure case be instituted in the United States District Court for

⁵ Compare, especially, R. 825-838 with R. 1105-1118, and R. 790 with R. 1138A, and the following statements (R. 818) "Think of our population, and think of all the common ailments," with (R. 1127) "Think of our population, and think of the number of cases of cancer, diabetes, heart trouble, high blood pressure, constipation, tuberculosis, arthritis, neuritis, and so on ad infinitum."

the District of New Jersey against a shipment of "Nutrilite Food Supplement" found in Belleville, New Jersey. Its labeling included a number of copies of the 58-page booklet (R. 188,332). The seizure was accomplished on October 6, the libel charging that the drug was misbranded when introduced into interstate commerce because of false labeling representations (R. 729, 751).

On September 30, 1948, another seizure recommendation came before Mr. Crawford based upon the same alleged misbranding (R. 333). Attached to the recommendation was a finding of fact in writing signed by Robert C. Butz, M. D., a medical officer of the Food and Drug Administration, stating that "Nutrilite Food Supplement," taken as directed, would not be effective in the treatment of "low vitality, over-fatigue, insomnia, poor appetite, gastro-intestinal distress, recurrent vague aches and pains, weak eyes, defective teeth, nervousness, heart disease, stomach pains, disease conditions requiring surgery, feeble-mindedness, diabetes, hemorrhage connected with the menopause, indigestion, sneezing, weeping, anemia, leukemia, sinus trouble, constipation, tuberculosis, headache, dizziness, vomiting, and all deficiency diseases" (Deft. Ex. 13, R. 1173-1174, 333, 334). With this medical finding before him, Mr. Crawford reexamined the booklet to determine whether the booklet represented Nutrilite to prospective purchasers as an effective treatment for those symptoms and

conditions (R. 334, 384). He concluded that there was probable cause to believe, and that he did believe, that the labeling of the drug would be in a material respect misleading to the injury or damage of the purchaser or consumer (Deft. Ex. 13, R. 1173, 333). This determination of probable cause was made as required under Section 304(a), *supra*, and thereafter three additional libel suits based upon the same alleged misbranding were recommended by the Federal Security Agency and were filed by the appropriate United States Attorneys (R. 729, 751).

Appellee then abandoned pages 37-58, ordered its salesmen to delete them from all booklets, and continued its sales campaign with the resulting 36-page version (Pl. Ex. 2, R. 844-882, 272, Pl. Ex. 11, R. 1024A, 273, 59-60, 188). On December 2, 1948, appellant George P. Larrick, Assistant Commissioner of Food and Drugs, made a probable cause determination on this booklet in circumstances substantially similar to those in which Mr. Crawford had acted. (Deft. Ex. 15, R. 1216, 408, 389, 395). The only difference was that the statements charged to be false and misleading were drawn from the first 36 pages of the booklet, the particular portions considered offensive being set forth in an exhibit attached to the finding of fact.⁶ One additional libel

⁶ This exhibit, although offered in evidence by appellants, was not admitted by the district court (R. 392, 408). The exhibit as offered is printed at R. 1218-1223.

suit was recommended by the Agency, and was consummated on December 15, 1948 (R. 408, 729, 751).

Shortly thereafter, representatives of the Food and Drug Administration in the field encountered a further revision of the booklet, this one 42 pages long (Pl. Ex. 3, R. 883-927, 272, 315, 188-189, 205).

A seizure recommendation came before appellant Dr. Paul B. Dunbar, Commissioner of Food and Drugs, on December 9, 1948 (R. 311-315). Dr. Dunbar was presented with a medical finding of fact that the drug, taken as directed, would not be effective in preventing or treating most common diseases (R. 1171-1172), and was given the 42-page booklet for his examination (R. 313-315). He concluded, after examining the booklet, that it seriously misbranded the drug by exaggerating its effectiveness in the prevention and treatment of "most common diseases", and he accordingly made his probable cause determination (Deft. Ex. 12, R. 1171-1172, 314, 315). Five seizure cases were filed on the basis of this finding (R. 729, 751).

The Complaint and Pre-Trial Proceedings. The present suit was filed in the United States District Court for the District of Columbia, on December 30, 1948, seeking to enjoin the prosecution of all of the libel suits except the one first filed and to prevent the filing of additional libel suits. No issue of constitutionality was raised (R. 689). On January 24, 1949, at a hearing on appellants' motion to dismiss the complaint on the ground that it

failed to state a claim upon which relief could be granted, Judge Pine questioned the authority of appellants Crawford, Larrick, and Danbar to act on behalf of the Federal Security Administrator in making the determinations of probable cause. (R. 593-4). However, he gave appellants an opportunity to present the matter to the Federal Security Administrator, and on January 28, Acting Administrator J. Donald Kingsley made the same probable cause determinations (Deft. Ex. 23, R. 1532-41, 518, 503). On March 4, Judge Pine granted the motion to dismiss the complaint (R. 724), with leave to amend to attack the constitutionality of Section 304(a) of the Act. (R. 608-609).

On that day, an amended complaint alleging substantially the same facts as were alleged in the original complaint but adding allegations of unconstitutionality, was filed (R. 725). Section 304(a) of the Act was alleged to be repugnant to the due process clause because it failed to afford appellee an opportunity for a hearing prior to the determination of probable cause (R. 733). Appellee prayed that appellants be ordered to dismiss all libel cases except the one first instituted; that the multiple seizure provisions of Section 304(a) be held invalid; and that a three-judge court be convened (R. 736). Judge Tamm granted a temporary restraining order on March 4, 1949. (R. 739). After a hearing on appellants' motion to dismiss, the three-judge court granted a temporary

injunction on April 6, 1949, without hearing evidence and without making findings of fact or conclusions of law (R. 741-742).

On April 14 notices to take depositions were served on Federal Security Administrator Ewing,⁷ Assistant Administrator Kingsley, Commissioner Dunbar, Assistant Commissioner Larriek, and three subordinate officials of the Food and Drug Administration in the Los Angeles area. The notices were followed by the service of *subpoenas duces tecum* which called for production of all records of the Agency relating to Mytinger & Casselberry, Inc., Lee S. Mytinger, William S. Casselberry, Nutrilite Products, Inc., Carl F. Rehnborg, and "Nutrilite Food Supplement." (R. 743-745.) Appellants moved to quash the subpoenas on numerous grounds (R. 746). A hearing was held before Judge Clark, who overruled appellants' objections (R. 747-748).

A pre-trial conference was held before Judge Tamm on April 13, 1949 (R. 643). Thereafter, a petition for writs of prohibition and/or mandamus was filed in this Court on the ground that the District Court proposed action in excess of its jurisdiction in undertaking a trial *de novo* on the issue whether the labeling was materially misleading. The petition was denied on May 16, 1949. 337 U.S. 902.

⁷ Mr. Ewing was absent from duty because of illness. Upon assurance from counsel that Mr. Ewing had not participated in the administrative decisions, he was excused from interrogation.

The Trial. The trial began before Judges Clark, Goldsborough, and Tamm on October 17 and was completed on October 27. Aside from reading into the record portions of the appellants' answer, admissions made under Rule 36 of the Federal Rules of Civil Procedure, and several memoranda taken from the files of the Food and Drug Administration (R. 58-59, 70, 273-283, 28, 48-49, 61, Pl. Ex. 4, R. 929-939, 47, Pl. Ex. 16, R. 1030 A, 69, 38-47, 64-65, 67-68, 269-271), appellee's case consisted of the testimony of William S. Casselberry, its president, and Dr. John A. Myers, and a deposition of Lee J. Myers, an attorney.⁸ In substance, their testimony was that appellee had acted in good faith in making the statements contained in the booklets; that, in their opinion, there was nothing in the booklets that was false or misleading; and that the statements contained therein conformed to the consensus of medical opinion. (R. 35-38, 50-53, 57-65, 75, 85, 86, 257-258.)

The three editions of the booklets were introduced into evidence. (Pl. Ex. 1, 2 and 3, R. 783-927, 272). The contents of the booklets are analyzed in Point III, *infra*, pp. 82-95.

⁸ The only other testimony, the deposition of Roger W. Truesdail, read into the record by appellee, declared that there would be a gradual loss of certain vitamin factors in multiple vitamin products with prolonged storage, and that there would be a loss of potency over the period of a year (R. 285). See p. 73, *infra*.

Cross-examination of Casselberry on specified passages in the booklet was not permitted (R. 230-233). At the court's suggestion, the questions ruled objectionable were embodied in a written "offer of proof" (R. 232-233), but when this offer of proof was presented, the court held that it was improper under rules "universal in every court in the United States", and rejected it (R. 520-528). After this ruling, the court also refused to permit the recall of Casselberry, who was present in the courtroom (R. 527-528).

Dr. Myers testified on direct examination that many common symptoms, such as headaches, gastric distress, lack of pep, fatigue, etc., reveal that widespread sub-clinical dietary deficiency diseases exist in the United States (R. 74-84, 86, 95, 145-147, 148), and that the vitamins and minerals in Nutrilite would be "helpful" for the symptoms mentioned in the booklet, though not necessarily sufficient to eradicate them completely (R. 86). On cross-examination, however, he testified that he understood the terms "common illnesses," "common diseases", "common deficiency diseases that cause death in the 40s and 50s," and "common dietary deficiency diseases", as used in the booklets (See R. 115-118), to include peptic ulcers, colds, sinusitis, colitis, eye trouble, diseases of cardio-vascular origin, arthritis, pneumonia, cancer, tuberculosis, nephritis, diabetes, etc. (R. 95, 97, 98, 100-115, 118, 121-122, 128, 135, 136, 138, 139):

and he admitted that in each of these "common illnesses" and "common diseases" vitamin pills alone would not cure or help (R. 99-102, 106-107, 112, 127-128, 131-132, 148, 163)..

The court stated, on several occasions during the course of the trial, that the booklets, as the court read them, represented only that the product would tend, by contributing to better general health, to increase the body's ability to withstand the inroads of disease, and thus in that sense to act as a preventative and not as a cure (R. 115-118, 122-127, 149-150, and see Finding 12(e) and (f), R. 759-760). For that reason, Judge Clark admonished counsel for appellants that the cross-examination had "gone far afield" (R. 115-116; 148) and cross-examination on Dr. Myers' understanding of various statements in the booklets was cut off (R. 181-183). Cross-examination as to the truth or falsity of claims drawn from testimonial letters found in pages 37-58 of the 58-page booklet was not permitted on the ground that counsel should not "twist" a testimonial into a representation of general applicability (R. 151-152), and that whatever possible misrepresentations there might be in the testimonials if they stood alone were fully explained in the first part of the booklet (R. 149-150).

At the conclusion of the appellee's case, the appellants moved for dismissal, urging that the evidence showed at most only that the booklets were not false or misleading to Casselberry, Mr. Myers

and Dr. Myers, and that this did not establish that the determinations of probable cause had no rational basis. The motion to dismiss was denied (R. 287-295).

The evidence offered by appellants fell into two categories: (1) testimony of the administrative officials concerned to show the basis for their determinations of probable cause; (2) testimony of three physicians not connected with the Government, and a Government expert on vitamins, and the deposition of Dr. Butz as to the medical facts on which the administrative officials based their determinations of probable cause.

Acting Administrator Kingsley's deposition, which had been taken by appellee, was read into the record by appellants (R. 501-518),⁹ and received in evidence (Deft. Ex. 22, R. 518). There were also received in evidence certified copies of the three determinations of probable cause made by Mr. Kingsley together with the supporting medical findings of fact of Dr. Butz. (Deft. Ex. 23, R. 1532, 518.) Mr. Kingsley's deposition stated that he had examined the editions of "How to Get Well and Stay Well" upon which his determinations were based, that he was an expert on standard propaganda technique, and that the total effect of the pamphlet, as well as of almost every page, was

⁹ A part of this deposition was read into the record by appellees (R. 269-270). Appellants exercised their right to read the remainder under Rule 26(d)(4) of the Rules of Civil Procedure for the United States District Courts.

misleading (R. 509-510, 512). He testified that "My decision was based upon the total impression of the publication rather than upon a particular sentence or paragraph. It employs a standard propaganda technique, first of all, of rousing strong emotion, which in this case, is fear, it seems to me, and then following through with the various kinds of suggestions. The whole thing seems to me to be very carefully calculated to produce a misleading impression" (R. 509), and that "the total impression [of the pamphlet] is a product of a substantial number of specifically misleading statements or impressions" (R. 510).

Appellants Crawford, Larrick, and Dunbar testified as experts with long experience in construing labeling and its impact on the consumer, and explained in detail how they had reached their conclusions that the pamphlets were materially misleading. Mr. Crawford testified that he had been with the Food and Drug Administration since 1917, that since 1918 one of his functions has been to review labeling and to evaluate the representations made to the public generally (R. 331-332), and that "this booklet [the 58-page version] fell into a very familiar pattern. It wins the reader's confidence right at the beginning by making statements of fact that everybody knows, and by professions of honesty and good will toward mankind, and then starts playing upon the scare technique, on persuading the reader that something is wrong with him.

* * * It creates an aura of honesty, an aura of good faith, for implications, innuendoes, inferences, that I believed when I read the book first—and believe now—are highly misleading, and are likely to be of great damage to consumers who are persuaded by this book or this material, and rely upon it for the purposes for which it is held forth in this book" (R. 334-336).

Mr. Crawford testified that the testimonials contained in the 58-page booklet would be accepted by the reader as representations that Nutrilite would be an efficacious treatment for the conditions, symptoms and diseases described therein (R. 336, 374-376). The court refused, however, to hear all of his testimony, because in the court's view, each testimonial merely represented the experience of one person and could be shown to be untrue only by proof that the testimonial giver had had no such experience (R. 376, 378-383). The court ruled, as a matter of law, that the testimonials were not intended to be, and could not be considered to be, general representations as to the beneficial effects of Nutrilite for the conditions mentioned therein (R. 152, 378-383).

Appellants Larrick and Dunbar testified similarly as to their lengthy service with the Food and Drug Administration and experience with labels and their effect on the consumer (R. 308-310, 385-387), that their opinions as to the representations made in the 36-page and 42-page booklets were simi-

lar to that of Mr. Crawford's with respect to the 58-page booklet, and that the booklets led readers to believe that Nutrilife offers an effective means of preventing and curing common and serious diseases such as ailments involving the heart and arteries, high blood pressure, coronary diseases, pneumonia, tuberculosis, and cancer (R. 326-327, 396, 398-400). Dr. Dunbar, Commissioner of Food and Drugs, testified that he had been with the Food and Drug Administration since 1907, that he had extensive experience in determining whether labels are misleading, and that "In making that survey of labels, it is always my effort to place myself in the position of the individual who is going to read that label and attempt to determine what impression the labeling will make on the person—the customer or purchaser—who reads that label" (R. 308, 310-311). He went through the 42-page booklet *seriatim*, and testified in detail as to the misleading statements contained in, and impressions conveyed, by, the booklet (R. 315-326). He stated that (R. 316-317):

A scare technique was being followed in the early part of this booklet to impress the prospective purchasers with the idea that almost everyone they met—members of their family, their friends, and they themselves—were afflicted with something or other that needed treatment or something terrible would happen.

It is quite a favored technique with those who in times past—and even to this day—are

selling various types of worthless patent medicines. It is very adroitly worded. There is a vast amount of factual statement in here, so I felt, that would create a fear complex in the mind of the purchaser.

I read the first six pages most carefully to determine whether that impression was carried out through the initial paragraphs of the book; then turned back and found further on that this product eventually is offered as the salvation of the individual who fears that he is afflicted with some of these diseases, or may be afflicted with those diseases.

These officials testified that, having drawn the conclusion that the booklets offered Nutrilite as a cure for common diseases and for a large number of symptoms, and being advised by medical findings of fact that the drug would not be effective in preventing or treating most common diseases or in treating the many symptoms and conditions expressly mentioned in the booklets, they had concluded that they had probable cause to believe that the labeling would be in a material respect misleading to the injury or damage of the purchaser or consumer (Deft. Ex. 12, R. 1171, 314; Deft. Ex. 13, R. 1173, 333; Deft. Ex. 15, R. 1216, 392, 408; Deft. Ex. 23, R. 1532, 518). To be sure, these witnesses did not have before them when the determinations of probable cause were made, facts showing actual physical injury or damage to any particular purchaser or consumer (R. 330, 385, 406, 507); but

each testified that his determination as to probable injury or damage to purchasers or consumers was based upon his conclusion that the labeling exaggerated the therapeutic value of the drug and that there was probable cause to believe that this labeling would cause consumers and purchasers in most cases to rely upon "Nutrilite Food Supplement" in treating conditions for which it was ineffective (R. 315-319, 335-336, 376-378, 395-405, 509-510). It was also testified that, in some cases, the labeling would cause them to delay in obtaining competent diagnosis and treatment for serious disease conditions with consequent irreparable damage to their health (R. 318, 403-404).

The appellants also presented medical and scientific testimony that vitamin and mineral deficiency diseases in this country today are rare (R. 340-341, 427-431, 442-444), and that a product of the composition of Nutrilite, taken in the recommended dosages and with the frequency prescribed, would not be efficacious for the prevention or cure of the diseases, conditions, and symptoms enumerated by Dr. Butz in his medical findings of fact or for the prevention or cure of so-called "common diseases" (R. 342-343, 344, 348-350, 351, 354-360, 362, 364-365, 432, 434, 437, 472-478).

Documentary evidence was introduced to prove that the booklet misrepresented (1) the significance of dietary disease as one of the causes of rejections among the W.A.C. (Deft. Ex. 4, R. 1059, 234) and

in the Selective Service System (Def't. Ex. 5, 19, 20, R. 1061, 1250, 1391, 465, 1063, 1068-1074, 1086-1099, 1264-1274, 1404-1411); (2) the results of a nutrition survey conducted by the Pennsylvania State College (Def't. Ex. 17, R. 1225, 456-457); (3) the educational background and professional standing of Carl F. Rehnborg (Def't. Ex. 24, R. 1542, 520); and (4) the role of dietary deficiency disease as a cause of death in the United States (Def't. Ex. 25, R. 1543, 529).

The findings and conclusions: The District Court made findings of fact and conclusions of law on December 14, 1949 (R. 756-771), holding that the multiple seizure provision of Section 304(a) under which the appellants had acted was unconstitutional under the due process clause of the Fifth Amendment (Concl. 2, R. 770); that the appellants had acted arbitrarily, oppressively, and capriciously in violation of the Fifth Amendment in instituting multiple libel proceedings without first affording the appellee a hearing on the probable cause question (Concl. 4, R. 770-771); and that the appellants should be permanently enjoined from instituting or maintaining any action raising a claim that Nutrilite is misbranded by the booklet "How to Get Well and Stay Well" (Concl. 5, R. 771).

The court found that the appellants had acted arbitrarily, capriciously and unreasonably in reaching their administrative determinations of probable cause (1) because the pamphlets when read as a whole, without lifting statements out of context,

are not fraudulent, false or misleading in any particular (Findings 12(e) and (f) R. 759-760); (2) because the administrative decisions permitted the institution of suits in widely separated jurisdictions (Finding 22 (R. 763-764)); (3) because appellants had placed reliance upon findings of fact made by Dr. Butz without talking to him about them; (4) because appellants had failed to rely upon a "survey",¹⁰ then in their files, which showed consumer reaction to the pamphlets; (5) because appellants had had before them no evidence of actual injury or damage to purchasers, and (6) because appellants had had insufficient knowledge as to the content of the pamphlets (Findings 17, 18, 29, 30, 31 and 35; R. 761-2, 765-768). The court also made a number of findings as to the appellee's good faith in attempting to comply with the law (Find-

¹⁰ The "survey" (Pl. Ex. 4, R. 929-939, 47) was a memorandum from one inspector of the Food and Drug Administration to the effect that he had interviewed seven users of Nutrilite, who did not believe that it was a cure-all but consisted of "vitamins and minerals which would build their bodies up." The memorandum pointed out that "None of these people were the rabid health addicts that one so often comes into contact with in an investigation of this type" (R. 930). Attached to the memorandum were five memoranda of interviews conducted by the inspector, which revealed that the purchasers were not using the drug as a preventative, but were using it for arthritis, anemia, hemorrhaging ulcers, and other serious diseases (R. 931-937). Although the court below treated this report as significant (Fdg. 30, 35 (R. 765-766, 767)), the administrative officials were obviously not bound to regard this statement of the views of seven persons as proof that the public would not be deceived by appellee's representations. In addition the memoranda were hearsay.

ings 8-10, 12-13, 19-20; R. 757-760, 762-763).¹¹ The court accordingly enjoined the maintenance and prosecution of all seizure actions, including the first instituted (R. 771-772), although the complaint had prayed only that all seizure actions other than the first be enjoined (R. 725, 736).

SPECIFICATION OF ERRORS TO BE URGED

1. The court erred in holding unconstitutional a portion of Section 304(a). (Asgt. 1, pp. 35-46, *infra*).

2. The court erred in holding that it had jurisdiction to review the administrative decisions as

¹¹ The Court found also that conduct of employees of the Food and Drug Administration before and after the administrative decisions also showed that the decisions were made arbitrarily. (Findings 9, 13-16, 21, 24, 26, 32, 37-42; R. 757-758, 760-761, 763, 764, 766, 768-770). The conduct deemed relevant to show that the decisions were made arbitrarily included: (1) the Food and Drug Administration's failure at all times to specify the exact statements in each pamphlet that were deemed to be false or misleading and to give the Company an opportunity to correct the labeling (Findings 9 and 40); (2) the interrogation of the Company's distributors and customers (Finding 13); (3) the "secret indictment" of Lee S. Mytinger and William S. Casselberry and the institution of the first libel without notice to the Company (Findings 14-16); (4) the failure to answer a letter which advised the defendants of the Company's good faith (Finding 21); (5) the institution of a libel suit contrary to the Company's understanding that no further actions were contemplated (Finding 24); (6) refusal to stipulate for removal of the cases to the Company's home district (Findings 26, 37); (7) placing city and State embargoes at the instance of the Food and Drug Administration (Finding 38); (8) giving unfavorable publicity regarding "Nutrilite" (Finding 39) and the preparation of an inter-office memorandum by an administrative subordinate in the Food and Drug Administration proposing a program for keeping pressure on the Company until there could be a determination on the merits of the controversy (Finding 32).

to whether there was probable cause to believe that the labeling of plaintiff's product would be in a material respect misleading to the injury or damage of purchasers or consumers. (Asgts. 4, 7, pp. 46-74, *infra*.)

3. The court erred in holding that it had jurisdiction to try in a *de novo* proceeding the question whether plaintiff's labeling was false or misleading in any particular or in a material respect to the injury or damage of purchasers or consumers. (Asgts. 2, 3, 7, pp. 74-76, *infra*.)

4. The court was clearly erroneous in finding that the administrative decisions of Dr. Dunbar, Mr. Crawford, Mr. Larrick, and Mr. Kingsley were made arbitrarily and capriciously. (Asgts. 8, 9, pp. 76-98, *infra*.)

5. The court was clearly erroneous in finding that the plaintiff's labeling is not fraudulent, misleading in a material respect to the injury or damage of purchasers or consumers, or false or misleading in any particular. (Asgt. 10, pp. 76-98, *infra*.)

6. The court erred in holding that plaintiff's good faith was a material issue in this case. (Asgt. 11, pp. 96-98, *infra*.)

7. The court erred in unreasonably curtailing the cross-examination of Dr. John A. Myers and Wil-

liam S. Casselberry, witnesses for the plaintiff. Asgts. 12-13, pp. 99-102, *infra*.)

8. The court erred in permitting the witness Casselberry to testify as an expert in the field of nutrition that there are no claims in the labeling that are untrue and that certain excerpts from medical and popular writings represented a good cross-section of medical opinion on questions of nutrition. (Asgts. 15, 16, pp. 105-106, *infra*.)

9. The court erred in admitting in evidence an exhibit offered by plaintiff which contained excerpts from medical and popular publications to prove medical opinions in the field of nutrition. (Asgt. 17, p. 105, *infra*.)

10. The court erred in rejecting a scientific article offered by the defendants as to the prevalence of dietary deficiency diseases even though the author, an outstanding man of science, was present for cross-examination. (Asgt. 18, pp. 104-105, *infra*.)

11. The court erred in permitting Dr. John A. Myers to testify to his understanding of what the labeling claimed for Nutrilite, and, upon his understanding of the labeling, that the said labeling did not represent that Nutrilite would cure all cases of dietary deficiency diseases or all cases of common diseases. (Asgt. 21, pp. 105-106, *infra*.)

12. The court erred in permitting Dr. John A. Myers, over defendants' objections, to testify that he found nothing in the labeling that was false or misleading, the said question requiring not only his expert opinions as a medical man but also an evaluation by him as to what the labeling would convey to the persons to whom it was directed. (Asgt. 22, pp. 105-106, *infra*.)

13. The court erred in permitting Lee J. Myers, an attorney and witness for the plaintiff, to testify that the statements in the labeling conformed to the consensus of informed medical opinion, and that the labeling was not false or misleading, misbranded or fraudulent, and would not cause injury or damage to the purchaser or consumer, the said questions requiring expert medical testimony, legal conclusions, and an evaluation of what the labeling would convey to the persons to whom directed. (Asgts. 23, 24, pp. 105-106, *infra*.)

14. The court erred in ruling that objections could not be taken at the trial to testimony in Lee J. Myers' deposition unless the objection was saved when the deposition was taken. (Asgt. 25, pp. 102-103, *infra*.)

15. The court erred in rejecting an official government publication which contained the vital statistics of the United States showing the major causes of death by age groups, which said publication was offered by defendants to disprove the labeling claims that dietary deficiency diseases were the

common diseases most responsible for death from illness. (Asgt. 27, pp. 103-104, *infra*.)

16. The court erred in refusing to permit Dr. E. M. Nelson, a witness for the defendants, to make comparisons between the daily dosage of Nutrilite and minimum daily requirements for the several vitamins and minerals contained therein as established pursuant to law by the Federal Security Administrator. (Asgt. 26, p. 107, *infra*.)

17. The court erred in admitting into evidence, over defendants' objections, memoranda of interviews with five persons prepared by an inspector of the Food and Drug Administration. (Asgt. 20, p. 24, note 10, *supra*.)

18. The court erred in allowing the plaintiff to probe the mental processes of the administrative officials in reaching their decisions. (Asgt. 5, pp. 108-109, *infra*.)

19. The court erred in denying defendants' motion to quash subpoenas duces tecum, served in connection with the oral interrogation of the Federal Security Agency defendants before trial, which required the defendants to deliver to plaintiff all records of the Food and Drug Administration relating to plaintiff, its predecessors, and its product, without requiring a showing of good cause under Rule 34 of the Rules of Civil Procedure for the United States District Courts. (Asgt. 6, pp. 108-109, *infra*.)

SUMMARY OF ARGUMENT

I

The court below held Section 304(a) unconstitutional to the extent that it allowed the administrative finding of probable cause to be made without a hearing. But this finding is merely preliminary to the institution of proceedings in court, which fully satisfied all constitutional requirements for a hearing. A great many decisions hold that due process does not require a hearing at the initial stage or any particular stage of an administrative proceeding, so long as an administrative or judicial hearing is held before any official binding order is entered. *E.g., Lichter v. United States*, 334 U.S. 742, 791-793; *Bourjois, Inc. v. Chapman*, 301 U.S. 183, 189. This principle applies *a fortiori* where the Administrator makes a mere preliminary finding of probable cause to institute a judicial proceeding. Any injury to appellee, while its product is detained until the outcome of the litigation, does not render unconstitutional the statutory scheme authorizing the suspension *pendente lite*, for the protection of the public, of allegedly unlawful activity. *Bowles v. Willingham*, 321 U.S. 503, 520; *Yakus v. United States*, 321 U.S. 414, 422-423; *Phillips v. Commissioner*, 283 U.S. 589, 596-597.

II

A. The District Court had no jurisdiction to review the administrative finding of probable cause.

This finding is merely a preliminary ruling such as the courts have consistently refused to review. Its only legal effect is as a condition precedent to a request that the Department of Justice institute libel proceedings, and even after the Department, in the exercise of its own authority, commences suit, the articles are condemned only after trial in a district court. Such administrative recommendations having no legal effect in themselves are not reviewable. *Chicago & Southern Air Lines v. Waterman S. S. Corp.*, 333 U.S. 103, 112-113; *United States v. Los Angeles and Salt Lake R. Co.*, 273 U.S. 299. This conclusion is not affected by the fact that the commencement of the litigation which will determine appellee's rights may in itself be expensive to the defending party. Cf. *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 51-52.

B. This general principle of non-reviewability is reinforced by specific manifestations of legislative intention that the administrative finding of probable cause was not to be reviewable. The very fact that Congress provided that the preliminary finding of probable cause be made without a hearing demonstrates that it was not to be judicially reviewed. Specific provisions of the Act for judicial review of other administrative determinations show that no review of the finding of probable cause was intended. *Switchmen's Union v. National Mediation Board*, 320 U.S. 297, 305-306. The history of the statute here involved also shows that power

to restrain multiple libels was eliminated from the bill after a preliminary administrative finding of probable cause was required. Furthermore, review of the administrative finding in an injunction suit prior to permitting multiple seizures would defeat the statutory purpose to stop distribution of a product deemed to be materially misbranded in a manner injurious or damaging to consumers before it reaches the public. The jurisdictional question here presented thus goes to the heart of the effectiveness of the scheme established by Congress to protect the public health and welfare.

C. The District Court also lacked jurisdiction as a court of equity because appellee had an adequate remedy at law. Section 304 allows a claimant of products libeled in more than one action to have the various proceedings consolidated for trial in a single district. Equity will not grant relief against a multiplicity of suits when the cases can be consolidated for trial. 1 Pomeroy, *Equity Jurisprudence* (5th Ed., 1941), pp. 495, 506, 511. Nor do the various types of injury alleged by appellee provide a basis for not giving effect to the carefully devised statutory procedure for consolidation.

D. The District Court also lacked jurisdiction to determine whether appellee's labeling was misleading. The preceding discussion of the statutory procedure shows that Congress intended this question to be decided by the court in which the libel proceedings are tried. To permit the basic issue as to

the deceptive character of the labeling to be decided in an injunction suit while the pending seizures were, at the command of the injunction court, held in abeyance, would be inconsistent with the basic purpose of Section 304 to protect the public during the period of pendency of the litigation. The injury to the owner of the products which often results when multiple seizures are begun was to be alleviated by consolidation, not by resort to a suit for injunction in the District of Columbia. The argument as to lack of equity jurisdiction is equally applicable to this aspect of the case.

III

If the District Court had jurisdiction to determine such issues, it should have found that the facts amply support the administrative determination of probable cause and that appellee's labeling is misleading. There was no substantial dispute in the medical testimony that Nutrilite, a vitamin and mineral product, would not cure or prevent most common diseases. The critical question was whether the administrative officials had reason to believe that appellee's booklets would give the reader a contrary impression. The 58-page booklet unquestionably represented, through testimonials, that Nutrilite was effective in the treatment of symptoms of serious diseases. Even after the testimonials were eliminated, a number of statements in the booklets were unquestionably false. And

an examination of the booklets as a whole, in the light of the conceded medical facts as to the inability of Nutrilite to cure or prevent most common diseases, demonstrates that they were designed to give readers a false impression that Nutrilite would prevent or cure all but acute ailments, and that almost everyone needed it in order to avoid dietary deficiency. See pp. 77-96, *infra*. "Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false." *United States v. 95 Barrels * * * Vinegar*, 265 U.S. 438, 442-443. "Advertisements as a whole may be completely misleading although every sentence separately considered is literally true." *Donaldson v. Read Magazine*, 333 U.S. 178, 188-189. The evidence of record demonstrates not only that the administrative finding was a reasonable one, but that the finding of the court below that the booklets were not misleading was utterly erroneous.

Appellee's good faith in issuing the booklets is irrelevant if they are misleading. *United States v. Dotterweich*, 320 U.S. 277, 281. Moreover, despite the finding below to the contrary, we think that the record clearly demonstrates that appellee was merely trying to avoid prosecution by the Government, not to be honest in its dealings with the public.

IV

If the Court should decide all of the above questions adversely to the Government, it becomes necessary to deal with the many errors committed by the District Court in the course of the trial. These consisted in brief of the improper curtailment of cross-examination of appellee's witnesses, incorrect rulings in excluding evidence offered by appellants and admitting, sometimes inconsistently, evidence offered by appellee, and improperly allowing interrogation of administrative officials and discovery of administrative records. In their cumulative effect, these errors seriously prejudiced the defense in the district court.

ARGUMENT

I

The Due Process Clause Does Not Prevent Congress from Authorizing Administrative Determinations of Probable Cause, Upon Which Institution of Multiple Seizure Suits Is Conditioned, to Be Made Without a Hearing

The original Food and Drugs Act of 1906 (34 Stat. 768, 771, Section 10) provided for the seizure of misbranded food and drugs "by a process of libel for condemnation." The Act in no way restricted the power of the Government to commence a number of separate condemnation proceedings against different shipments of the same article, and such multiple seizures were not uncommon.

When the food and drug legislation was revised in 1938 and embodied in the present Federal Food,

Drug, and Cosmetic Act, the libel for condemnation provision was incorporated in Section 304(a) (52 Stat. 1040, 1044, 21 U. S. C. 334). The revised provision limits the authority of the Government to institute more than one libel proceeding against different shipments of the same misbranded product¹² by requiring compliance with one of certain conditions before more than one such proceeding can be instituted.¹³ The provision pertinent to the constitutional issue here is that which permits the institution of more than one libel for condemnation "when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer." Section 304(b) provides that when more than one condemnation proceeding is filed, the claimant can have the proceedings consolidated for trial.

¹² If there has been a prior judgment in favor of the United States, or if the drug is libeled because it is "adulterated," as distinct from misbranded, there is no bar whatever to multiple actions based upon the same charge. "Adulteration" is used in the statute in a special sense. Sections 402, 501. The Act provides its own glossary. *United States v. Coca Cola Co.*, 241 U. S. 265. For example, a drug is deemed to be "adulterated" if it fails to meet standards of strength, quality, or purity prescribed in the United States Pharmacopoeia.

¹³ The history of the libel provisions is discussed at greater length in Point II, pp. 52-58, *infra*.

The court below concluded that (R. 770):

The following provisions [of the Act] * * * are unconstitutional under the due process clause of the Fifth Amendment to the Constitution of the United States: " * * * such limitations shall not apply * * * when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employe of the agency that * * * the labeling of the misbranded article * * * would be in a material respect misleading to the injury or damage of the purchaser or consumer."

The court did not write any opinion expressly indicating the basis for its conclusion as to the invalidity of the quoted portion of the statute. It is clear from the record and findings, however, that the court was of the view that the constitutional defect resided in the provision permitting the Administrator to act without hearing. It is not entirely clear whether the decision below means (a) that the Constitution precludes the institution of more than one judicial proceeding against different shipments of an article, in the absence of a prior administrative hearing, or only (b) that, if Congress provides for an administrative finding as prerequisite to suit the Constitution requires that such finding must be preceded by a hearing.

If the first theory is the basis for the decision below, the Food and Drugs Act would have been

unconstitutional since 1906, inasmuch as prior to the 1938 Act there was no requirement for any administrative action at all before the commencement of more than one condemnation proceeding. Furthermore, even the present Act contains no limitation upon the right to make multiple seizures of products which are adulterated (Sec. 304). It is more likely, therefore, that the decision below was predicated upon the second theory, and that the statute was held unconstitutional because the 1938 limitation upon the power of the Government to bring more than one action¹⁴ in condemnation permits an administrative finding without a prior hearing.

It is unnecessary, however, to resolve these doubts as to the precise legal theory embodied in the decision below. For many holdings of this Court demonstrate the unsoundness of either theory and the validity of the statute as enacted and as here applied.

The administrative finding of probable cause required by Section 304(a) is merely the prerequisite to the bringing of a lawsuit. Not until the Administrator has made the required finding is he in a position to request the Department of Justice to institute more than one condemnation proceeding against different shipments of the mis-

¹⁴ The decree, however, also enjoins the first libel (R: 771-772), as to which no administrative finding of probable cause is required by the statute.

branded product. After the finding has been made, the Department may file libels for condemnation, accompanied by seizures of the property in question against different shipments. The owner of the property then has an opportunity to appear as claimant, and he is entitled to a full hearing before a district court in which one libel has been filed or to which the various cases may be removed and consolidated for trial. The statute (Section 304(b)) provides that the procedure shall conform to the "procedure in admiralty," except that on demand of either party trial shall be by jury.

Such a trial in court fully satisfies all constitutional requirements. We have been unable to discover any authorities to support the notion that the due process clause of the Constitution requires an administrative hearing in order to determine whether there is probable cause for instituting a judicial proceeding in which the matter will be fully tried.

On the contrary, a great many decisions of this Court show plainly that the due process clause has never been regarded as containing any such unreasonable requirement. The Court has stated in at least three recent cases that "the demands of due process do not require a hearing, at the initial stage or at any particular point or at more than one point in an administrative proceeding so long as the requisite hearing is held before the final order becomes effective." *Lichter v. United*

States, 334 U. S. 742, 791-792; *Inland Empire Council v. Millis*, 325 U. S. 697, 710; *Opp Cotton Mills v. Administrator*, 312 U. S. 126, 152-153. See to the same effect *Bowles v. Willingham*, 321 U. S. 503, 519-520. In each of the cases cited, the statute permitted an administrative agency to make a preliminary determination, after which a full administrative hearing was available to any aggrieved party.

The principle enunciated in those decisions would seem to have particular force where, as here, the subsequent hearing is to be held before a court in lieu of an administrative body. Many cases have held that an administrative hearing is not essential to due process where no final action takes place until after the case has been heard by a court. In 1918 this Court stated that "this, as repeatedly has been held, satisfies the requirements of due process of law." *Wells-Fargo & Co. v. Nevada*, 248 U. S. 165, 168. Other cases to the same effect are *Bourjois, Inc. v. Chapman*, 301 U. S. 183, 189; *Utley v. St. Petersburg*, 292 U. S. 106, 109; *Niskey v. Mississippi*, 292 U. S. 393, 396; *American Surety Co. v. Baldwin*, 287 U. S. 156, 168; *Coffin Bros. v. Bennett*, 277 U. S. 29, 31; *Mount St. Mary's Cemetery v. Mullins*, 248 U. S. 501, 506; *Pittsburgh &c. Railway v. Board of Public Works*, 172 U. S. 32, 45; *Wilson v. Standefer*, 184 U. S. 399, 415; *Gallup v. Schmidt*, 183 U. S. 300, 307; *Winona & St. Peter Land Co. v. Minnesota*, 159 U. S. 526, 537; *Hagar v. Reclamation District*, 111 U. S. 701.

In most of the cases cited, the administrative or taxing agency made a determination as to the merits of the matter in issue before the question was submitted to a court. The correctness of the Government's position in the present case would seem to follow *a fortiori*. Here the Administrator made a mere preliminary finding. He did not finally adjudicate the contraband character of the drug. He did not purport to decide the question which would be before the court, but only whether there was probable cause to believe that the product had been materially mislabeled, sufficient to warrant the institution of the judicial proceeding. In other words, the Administrator, far from making any definitive adjudication, merely found that the facts presented an issue for adjudication by a court. Even in the absence of the express provision of the statute that such a preliminary finding could be made "without hearing," a hearing would not have been required as a condition precedent to the making of such a determination. Compare *Isbrandtsen-Moller Co. v. United States*, 300 U. S. 139, 149. While the Constitution may require a hearing by an administrative agency when an issue is committed to administrative adjudication rather than to judicial determination, it obviously does not require an administrative hearing as a prerequisite to an administrative agency's right to report facts to prosecuting officials for trial and determination in a district court. The Constitution does not require that those functions of Gov-

ernment that traditionally have been conducted as investigative and reporting activities preliminary to a lawsuit be conducted by judicial methods. Cf. *United States v. Morton Salt Co.*, 338 U. S. 632, 641.

Probably the closest analogy is the institution of criminal proceedings by an indictment returned by a grand jury. The grand jury determines, in substance, that there is probable cause to believe that the accused is guilty; the result is that the defendant may be arrested and held for trial. *Beavers v. Henkel*, 194 U. S. 73, 84. The proceeding before the grand jury is obviously not a "hearing" in the usual sense, inasmuch as the defendant has no right to appear and present his own witnesses or to cross-examine the Government's witnesses. Clearly, if such a hearing is not essential to a finding of probable cause when the liberty of an individual is at stake, the same must be true with respect to a similar administrative finding which serves as a statutory prerequisite to the institution of legal proceedings affecting an individual's property. This Court has recognized that "the finding of an indictment, fair upon its face, by a properly constituted grand jury, conclusively determines the existence of probable cause for the purpose of holding the accused to answer." *Ex parte United States*, 287 U. S. 241, 250. The Constitution can require no more as to a determination

of probable cause made "for the purpose of holding" food or drugs alleged to be misbranded.

Appellee will doubtless argue that the withholding of the seized property until the conclusion of the libel action is injurious, both because of the interference with its business operations during the interim and because the quality of the product may deteriorate,¹⁵ even though the product will eventually be returned if the Government[®] does not establish its case. But injury of this sort does not render unconstitutional judicial proceedings in which a defendant is temporarily restrained from continuing his allegedly unlawful conduct *pendente lite*. The public interest has often been held to justify a temporary and probably costly suspension of activities claimed by the Government to be unlawful and injurious to the public interest. In *Phillips v. Commissioner*, 283 U. S. 589, 596-597, in language reaffirmed in *Bowles v. Willingham*, 321 U. S. 503, 520, the Court declared:

Where only property rights are involved, mere postponement of the judicial enquiry is not a denial of due process, if the opportunity given for the ultimate judicial determination of the liability is adequate. *Springer v. United States*, 102 U. S. 586, 593; *Scottish Union & National Ins. Co. v. Bowland*, 196 U. S. 611, 631. Delay in the judicial determination of

¹⁵ As to the degree and rate of deterioration, see pp. 73-74, *infra*.

property rights is not uncommon where it is essential that governmental needs be immediately satisfied. For the protection of public health, a State may order the summary destruction of property by administrative authorities without antecedent notice or hearing. Compare *North American Cold Storage Co. v. Chicago*, 211 U. S. 306; *Hutchinson v. Valdosta*, 227 U. S. 303; *Adams v. Milwaukee*, 228 U. S. 572, 584. Because of the public necessity, the property of citizens may be summarily seized in war-time. *Central Union Trust Co. v. Garvan*, 254 U. S. 554, 566; *Stoehr v. Wallace*, 255 U. S. 239, 245; *United States v. Pfitsch*, 256 U. S. 547, 553. Compare *Miller v. United States*, 11 Wall. 268, 296; *International Paper Co. v. United States*, 282 U. S. 399; *Russian Volunteer Fleet v. United States*, 282 U. S. 481. And at any time, the United States may acquire property by eminent domain, without paying, or determining the amount of the compensation before the taking. Compare *Kohl v. United States*, 91 U. S. 367, 375; *United States v. Jones*, 109 U. S. 513, 518; *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U. S. 290, 306.

The *Phillips* case held that the collection of taxes could be enforced in advance of the opportunity to litigate their validity. In *Yakus v. United States*, 321 U. S. 414, 442-443, the Court sustained the provision of the Emergency Price Control Act permitting the minimum prices established by the Administrator to remain in effect pending their

review in the courts. This Court stated (321 U. S. at 442):

Our decisions leave no doubt that when justified by compelling public interest the legislature may authorize summary action subject to later judicial review of its validity.

The *Yakus* opinion then proceeded to give the same illustrations found in the above quotation in the *Phillips* opinion, and to add others.

Both the *Phillips* and *Yakus* opinions cite, as a prominent example of the right of the State to act without a prior hearing, the cases permitting the summary destruction of property for the protection of the public health. The label provision of the food and drug legislation, which is modeled on the procedure in admiralty, does not go nearly that far. It provides only for the interim protection of the public against the distribution of food and drugs believed to be dangerous to health or misbranded in a fraudulent or materially misleading respect, by holding the products until the legality of the branding has been determined. In view of the great harm which members of the public may suffer if even harmless articles are allowed to be sold as panaceas for illness or disease, there can be no question as to the reasonableness and fairness of a statutory procedure which treats the interest of the public, *pendente lite*, as superior to that of the owner of the product. Cf. *Yakus v. United States*, 321 U. S. at 437-443.

The District Court Had No Jurisdiction to Review the Administrative Determination of Probable Cause or to Decide Whether Appellee's Labeling Was Misleading

The formal "Conclusion of Law" entered by the court below (Conclusion 4, R. 770-771) was that the officials of the Food and Drug Administration had acted arbitrarily in instituting multiple libel proceedings without first affording the appellee a hearing on the issue of whether there was probable cause to believe that its labeling was fraudulent or misleading in a material respect. Obviously, the mere failure to grant appellee a hearing could not be arbitrary or capricious or oppressive, if we are correct in our previous contention that Congress could constitutionally provide that the determination of probable cause could be made without a hearing. If the statute is valid, the officials did not violate the Constitution merely by following the express terms of the law.

The court below also held, in accordance with appellee's contentions, that the administrative officials acted capriciously, arbitrarily and unreasonably in making their decisions with respect to appellee's product (Fdg. 43, R. 770). The plain implication of this finding would seem to be that the determinations of probable cause were invalid because the officials who made such determinations had no rational basis for their actions. Furthermore, the court also held that the labeling of ap-

pellet's product was not false and misleading in any particular (Fdg. 12(f), R. 759-760).¹⁶

It is our contention that the court lacked jurisdiction to pass upon these issues. The finding serves merely as a condition precedent to a recommendation for the institution of judicial proceedings, and under established principles is not ripe for review. Furthermore, whether the labeling was misleading was intended to be determined in the condemnation proceedings. In addition, we shall show that since the statute provides an adequate remedy at law for persons against whose product more than one libel is instituted, the court below, as a court of equity, lacked jurisdiction to decide these issues in this injunction suit brought against the administrative officials.

A. Preliminary Administrative Rulings Which Are Mere Prerequisites to the Commencement of Additional Proceedings Are Not Reviewable

The Administrator's finding of probable cause is not reviewable since it is only a preliminary ruling of a sort which the courts have consistently refused to review. The finding is, it is true, a necessary prerequisite to the commencement of more than a single libel action based upon the same alleged misbranding. But the only positive effect of a finding is to enable the Administrator to re-

¹⁶ These conclusions, though contained in the formal Findings of Fact, rather than in the Conclusions of Law, are in fact legal conclusions. They clearly constitute a part of the reasoning of the court below in support of its judgment.

quest the Department of Justice to cause the libels to be instituted. The Department is not bound to accept the Administrator's recommendation.¹⁷ Even if it should do so, it only initiates the proceeding, and the drugs may be condemned only after trial by the district court.

In *Chicago & Southern Air Lines v. Waterman S. S. Corp.*, 333 U. S. 103, 112-113, and *United States v. Los Angeles and Salt Lake R. Co.*, 273 U. S. 299, this Court was also requested to review administrative rulings which were conditions precedent to the entry of final decisions but which in themselves had no binding legal consequences. The final valuations of the Interstate Commerce Commission which were before the Court in the *Los Angeles and Salt Lake* case were made "prima facie evidence of the value of the property" in subsequent rate proceedings (273 U. S. at 310-311). The decisions of the Civil Aeronautics Board such as were involved in the *Chicago & Southern* case are under the statute necessary prerequisites to Presidential action. The President need not follow the Board's recommendations, though he generally

¹⁷ * * * while the Attorney General, in the performance of his official duties, has power to decide, or delegate power to decide, whether a particular statute has been violated and, if so, whether to initiate prosecution, his judgment is not in any way controlled by a report from the Federal Security Administrator, much less by the declaration or recommendation of an officer subordinate to the Federal Security Administrator; specifically, he is under no 'mandatory duty' to do anything under such circumstances." *Helck Products Co., Inc. v. McNutt*, 137 F. 2d 681, 683 (C.A. D.C.).

does. As the Court stated in the *Chicago & Southern* case, the Board's decision "may be a step which if erroneous will mature into a prejudicial result, as an order fixing valuations in a rate proceeding may foreshow and compel a prejudicial rate order." But, the Court continued, "administrative orders are not reviewable unless and until they impose an obligation, deny a right or fix some legal relationship as a consummation of the administrative process."

This principle that preliminary or intermediate agency action shall not be directly reviewable is also recognized in Section 10(c) of the Administrative Procedure Act.¹⁸

It may be suggested that the administrative finding of probable cause does constitute the "consummation of the administrative process," inasmuch as the Administrator himself takes no further action. But his finding results only in a recommendation that the Department of Justice proceed. It is apparent that his finding is not the conclusion of the administrative process, even if the subsequent judicial participation in the proceedings be disregarded.

¹⁸ "Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action." Section 10(c), 5 U.S.C. 1009(c).

But if it be assumed that the intervention of the Department of Justice between the Administrator and the district court may not be taken into account, on the ground that the Department is an automatic conduit for the Administrator's wishes—which it is not—appellee is in no better position. For it cannot be said that an administrative finding which is a condition precedent to a trial *de novo* in a court before rights are determined is any more reviewable than a finding which serves merely as a prerequisite to further administrative proceedings. If anything, the reasoning of the decisions cited would seem to apply even more clearly in the former case.

The finding of probable cause prior to the institution of legal proceedings is by no means peculiar to the Food, Drug, and Cosmetic Act. The function of the grand jury is to determine whether there is "probable cause" to believe that a defendant is guilty before subjecting him to the burden of trial. *Beavers v. Henkel*, 194 U. S. 73, 84. But persons charged with crime cannot sue to enjoin prosecution on the ground that the evidence before the grand jury was insufficient to show probable cause. Indeed, they are not entitled to any trial of that issue. *Ex parte United States*, 287 U. S. 241, 250, quoted at p. 42, *supra*. Although the grand jury proceeding is a guarantee against arbitrary action, it does not accord the defendant a chance to try his case twice—or even to have a hearing upon the

question of probable cause at all. See p. 42, *supra*. The language of this Court, although uttered in a factually different connection in *Beavers v. Henkel*, which involved removal proceedings after indictment, sets forth the general considerations relevant here:

The thought is that no one shall be subjected to the burden and expense of a trial until there has been a prior inquiry and adjudication by a responsible tribunal that there is probable cause to believe him guilty. But the Constitution does not require two such inquiries and adjudications. The government, having once satisfied the provision for an inquiry and obtained an adjudication by the proper tribunal of the existence of probable cause, ought to be able without further litigation concerning that fact to bring the party charged into court for trial. [194 U.S. at 84-85.]

The indictment alone was, as we have seen, a showing of probable cause sufficient to justify the issue of a warrant. [194 U.S. at 87.]

Appellee may urge that the finding of probable cause should not be treated as merely preliminary in nature since the institution of more than one libel proceeding, with the resultant seizures, will cause it financial injury. But the commencement of litigation is often expensive or otherwise harmful to the defending party. See *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 51-52. The grand jury's non-reviewable finding of probable cause may result in immediate arrest and imprisonment. This will

generally be true when the commencement of legal proceedings is accompanied by the seizure of property. In none of these situations will a court of equity in a separate injunction suit interfere with the normal processes of litigation by predetermining the issues in order to prevent injury *pendente lite*. Here, Congress has determined, through its establishment of the libel procedure, that the claimant and not the public must endure possible injury during the pendency of the litigation. See pp. 43-45, *supra*. Such a legislative determination should not be frustrated by permitting this type of injunction suit to be maintained.

B. The Statute and Its History Show That the Administrative Finding of Probable Cause Was Not Intended to Be Subject to Judicial Review

In addition to the general considerations just referred to, the history of the Federal Food, Drug, and Cosmetic Act shows that the administrative finding of probable cause was not intended to be subject to judicial review.

1. The History of the Pertinent Statutory Provisions.

As has been noted, under the Federal Food and Drugs Act of 1906, 34 Stat. 768, 771, goods that were adulterated or misbranded were subject to seizure wherever found, and multiple seizures were regularly made. The Act of 1906 was revised comprehensively in 1938. Long and careful consideration, extending from the 73d to the 75th Congresses, was

given to the redrafting of the section relating to libels and seizures, with particular reference to the problem of multiple libels. Bills originally proposed provided for *executive* seizures of articles "dangerous to health"¹⁹ and placed no limitation on the number of libel suits that might be brought.

Subsequently, the legislation was redrafted to grant to the United States District Courts jurisdiction to restrain a multiplicity of seizures based upon the same alleged misbranding unless the misbranding involved danger to health or "gross deception," or unless it had been the basis of a prior judgment in favor of the United States.²⁰ That bill would have authorized suits of the kind here involved.

Still later, the Senate accepted an amendment which would have placed upon the administrative agency the duty to "show cause" in a United States District Court why multiple seizures were necessary.²¹ This would have permitted a judicial determination of "probable cause" such as appellees have obtained in this case.

During the progress of the bill through the 74th Congress, after the addition of the requirement of

¹⁹ S. 2000, and S. 2800, 73d Cong., 2d Sess., Sec. 16(a). These bills appear in Dunn, *Federal Food, Drug, and Cosmetic Act* (1938), pp. 52, 71, which contains a complete statement of the legislative history of the Act. See also S. 5, Sec. 711, Dunn, p. 232, and S. Rep. 361, 74th Cong., 1st Sess., p. 29, Dunn, p. 263.

²⁰ S. 2800, as reported to Senate, February 6, 1934, 73d Cong., 2d Sess., Sec. 19(c), Dunn, pp. 105-106.

²¹ S. Rep. 361, 74th Cong., 1st Sess., Part 2, p. 11; 79 Cong. Rec. 5230-5231, Dunn, pp. 389, 399, 467-469.

an administrative finding of probable cause, and the provisions for consolidation,²² the provisions authorizing executive seizures and judicial "show cause" proceedings were dropped.²³ The House Committee in the 74th Congress also eliminated the provision of the Senate bill that would have granted the district courts jurisdiction to restrain a multiplicity of libel actions.²⁴

The Senate bill at this stage only allowed multiple seizures (in the absence of a prior judgment) where misbranding rendered the article "imminently dangerous to health."²⁵ The House Committee rejected this limitation (Dunn, p. 528), and added a provision authorizing multiple seizures in cases where the Secretary had probable cause to believe that the misbranding was "in a material respect false, misleading or fraudulent."²⁶ The House Committee Report²⁷ stated with respect to

²² S. 5, as reported to Senate, January 3, 1935, 74th Cong., 1st Sess., Sec. 711(c), Dunn, 213, 233.

²³ 79 Cong. Rec. 8354, Dunn, pp. 505-506.

²⁴ H. Rep. 2755, 74th Cong., 2d Sess., p. 10, Dunn, pp. 529, 558. The Committee Report stated in this connection: "This subsection was struck out because it seemed to the committee to be either unnecessary or else susceptible of the possible construction that it might give each district court authority to issue injunctions which would operate throughout the United States."

²⁵ 79 Cong. Rec. 5230-5231, Dunn, pp. 467-469; S. Rep. No. 646, 74th Cong., 1st Sess., p. 13, Dunn, pp. 488-489.

²⁶ S. 5, as reported in H. Rep. No. 2755, 74th Cong., 2d Sess., May 22, 1936, 80 Cong. Rec. 7830, Dunn, pp. 546, 558.

²⁷ H. Rep. 2755, 74th Cong., 2d Sess., p. 9, Dunn, pp. 550, 558.

this modification, which in substance conforms closely to the Act as finally passed:

There are two substantive changes made by this committee. One is that multiple seizures would be permitted in cases where the Secretary has probable cause to believe that the misbranding is in a material respect false, misleading, or fraudulent. This will permit protection of the public against such nostrums as a brew of weeds labeled as a treatment for diabetes and against innumerable other cheats and frauds which at best rob the consumer's pocketbook, and at worse rob him of health or life through his mistaken reliance upon them while his disease progresses unchecked. With this change the seizure section will continue to function as a means of "arresting the bullet in flight before it claims its victim", although the administrative agency will have materially less latitude, in making multiple seizures, than it has had under the present law for the past 30 years.

The Senate agreed to the House provision in a compromise bill,²⁸ but the bill did not pass the House at that session for other reasons.²⁹

Substantially the same version of this provision was included in S. 5 as introduced in the 75th Congress (Dunn, p. 642), but the Senate Committee in reporting the bill omitted the language previously

²⁸ 80 Cong. Rec. 10544, 10518, 10520, Dunn, pp. 598, 613-614, 619.

²⁹ 80 Cong. Rec. 10674-10680, Dunn, pp. 620-633.

added by the House.³⁰ Prior to passage in the Senate, a clause was added permitting multiple seizures if the misbranding "is in a material respect false *and* fraudulent, or is labeled or advertised as a cure or remedy for cancer," and other named diseases.³¹ The House, nevertheless, adhered substantially to the language which it had proposed at the previous Congress, which included, in addition to the phrase "dangerous to health," misbranding which was "in a material respect false *or* fraudulent."³² The

³⁰ S. 5, as reported in 75th Cong., 1st sess., February 15, 1937, p. 14, 81 Cong. Rec. 1194, Dunn, pp. 655, 662; S. Rep. 91, 75th Cong., 1st sess., p. 4, Dunn, pp. 678-679.

³¹ 81 Cong. Rec. 2007, 2013, Dunn, pp. 709-710, 725, 726.

³² S. 5 as reported to House, April 14, 1938, 83 Cong. Rec. 5465, Dunn, pp. 780, 798; H. Rep. No. 2139, 75th Cong., 3d sess., p. 4, Dunn, p. 818; 83 Cong. Rec. 7790, 7903, Dunn, pp. 892, 963. H. Rep. No. 2139, p. 4, Dunn, p. 818, makes it clear that the object of the change from the Senate version was "to make proof of intent to deceive unnecessary. The report states:

Multiple seizures may be made on adulterations and on misbranding "when the Secretary has probable cause to believe that the misbranded article is dangerous to health or that the labeling of the misbranded article is, in a material respect, false or fraudulent." This represents substantially the administrative policy followed by the Department of Agriculture in the more than 30 years the old law has been enforced.

The language adopted by your committee differs from that of the Senate act in that in the provision above quoted, the words "false and fraudulent" rather than "false or fraudulent" are used. If a misbranding is sufficiently serious to justify the removal of the product from the market to safeguard the consumer against harm, then it is wholly immaterial whether the falsity of the labeling is a matter of gross carelessness or inadvertence, or whether it was grounded on a deliberate intent to deceive. Since the seizure procedure is peculiarly adapted to the enforcement of a consumer-protective law in that it arrests the illegal goods before the consumer is harmed,

conferees accepted the substance of the House proposal, substituting "in a material respect misleading to the injury or damage of the purchaser or consumer" for "in a material respect, false."³³ Representative Lea, in explanation for the House conferees, stated:³⁴

The object of that change was to make it clear that the misleading statement which it was intended to prohibit by seizure should be of such character as it might mislead a customer or purchaser to his damage. It has in mind consumer protection.

The language finally adopted conformed in substance to what the House had continually insisted upon. Although the Senate proposals had not gone as far, it is clear that the bill as passed included language which was deliberately selected so as to permit multiple libels with respect to products which were in themselves not dangerous to health but which because of their misbranding might be harmful to consumers.³⁵

your committee has been careful to avoid restricting this form of action in cases where there is actual need for its exercise to protect health or prevent fraud.

³³ See Conf. Rep., H. Rep. 2716, 75th Cong., 3d sess., pp. 5, 22, 83 Cong. Rec. 9089, 9094, Dunn, pp. 974, 992-993.

³⁴ 83 Cong. Rec. 9095, Dunn, pp. 997, 998.

³⁵ We have felt it necessary to set forth this legislative history in detail because of the repeated statements of Judge Clark during the proceedings below (R. 17, 679) that "That provision was slipped into the conference report; * * * it was slipped in in conference, * * * Nobody knew anything about the amendment." Judge Clark had as Senator

The Conference Report which reported the bill as finally passed inserted the words "without hearing" into the provision requiring the Administrator to make a preliminary finding of probable cause.³⁶ There was no explanation of this change, presumably because its meaning and purpose were obvious.

2. No Review of the Administrative Finding of Probable Cause was Intended.

(a) The above summary of the history of the libel provisions of the present statute shows that the bill at one stage specifically gave the United States District Courts power to restrain multiple seizures. But this provision was eliminated after the bill was amended to require an administrative finding of probable cause as a condition to the institution of multiple libel proceedings in the district courts. Thus Congress considered and rejected granting the district courts jurisdiction to determine by injunction whether multiple seizures should be allowed. The scheme whereby a preliminary finding of probable cause was required, and the consolidation of multiple suits permitted, was evidently thought to give the owner of the property adequate protection.

been a member of the Conference Committee which, without dissent, approved the bill. H. Rep. No. 2716, 75th Cong., 3d Sess., p. 21, 83 Cong. Rec. 9094, Dunn, p. 992.

³⁶ H. Rep. 2716, 75th Cong., 3d Sess., pp. 5, 22, 83 Cong. Rec. 9089, 9094, Dunn, pp. 974, 992-993.

(b) The very fact that Congress provided that the preliminary determination of probable cause was to be made without a prior administrative hearing demonstrates that it was not intended to be reviewable at a subsequent judicial hearing. In the absence of an administrative hearing, there will be no record, in the usual sense, for a court to review. Judicial review therefore means, as the present case demonstrates, that, in order to determine whether there was sufficient basis for a preliminary finding, there may be a trial of substantially the same issues as would be canvassed at the libel trial on the merits. Since the reasonableness of the finding depends in large part upon whether the representations in question seem to be misleading, such review would usually, as here, become a *de novo* inquiry into the truth or falsity of the labeling. Furthermore, judicial reexamination of the preliminary administrative determination of "probable cause" might require testimony from the highest officials of the administrative agency as to what was before them and the reasons for their action (but compare *United States v. Morgan*, 313 U. S. 409, 422). Thus to allow review of a preliminary finding would in fact result in a full-scale trial in order to determine whether there was probable cause to institute a judicial proceeding which would in itself eventuate in a trial of perhaps considerably smaller dimensions. Clearly, there is nothing in either the text or the history of the

legislation which even suggests that Congress intended its provision for a preliminary finding of probable cause to result in one lawsuit to determine whether there should be another. The same considerations—avoidance of needless delay, adequacy of protection afforded to owner, etc.—which persuaded Congress to dispense with an administrative hearing, also militate against reading into the Act a provision for judicial review at that stage of the proceeding.

(c) When Congress intended administrative determinations under the Federal Food, Drug and Cosmetic Act to be judicially reviewable, it said so. Several sections of the Act authorize review of administrative action. (Sections 505(h), 701(e) and (f), 21 U. S. C. 355(h) and 371(e) and (f)). Section 701, in particular, provides for review of many types of administrative orders.³⁷ The absence of any such provision with respect to the preliminary finding of probable cause manifests a legislative intent that there be no review of such a finding, much more clearly than in the statute before the Court in *Switchmen's Union v. National Mediation Board*, 320-U.S. 297.³⁸ The language of the Court in that

³⁷ Section 701(f) authorizes judicial review by the United States courts of appeals of administrative action under Sections 401, 403(j), 404(a), 406(a) and (b), 501(b), 502(d), 502(h), 504, 506, 507, and 604 of the Act. 21 U.S.C. 341, 343(j), 344(a), 346(a) and (b), 351(b), 352(d), 352(h), 354, 356, 357, and 364.

³⁸ Section 10 of the Administrative Procedure Act, 5 U.S.C. 1009, in its introductory clause, excepts agency action from

case is peculiarly applicable here (320 U.S. at 305-306) :

That conclusion is reinforced by the highly selective manner in which Congress has provided for judicial review of administrative orders or determinations under the Act. There is no general provision for such review. But Congress has expressly provided for it in two instances. * * * When Congress in § 3 and in § 9 provided for judicial review of two types of orders or awards and in § 2 of the same Act omitted any such provision as respects a third type, it drew a plain line of distinction. And the inference is strong from the history of the Act that that distinction was not inadvertent.

The deletion from the original bill here of provisions for injunctive relief against multiple seizures, after the probable cause finding was required, makes it clear that the failure to provide for review of the probable cause determinations was no more inadvertent in the Food, Drug, and Cosmetic Act than in the Railway Labor Act.

(d) The consequences of permitting judicial review of the finding of probable cause would to a considerable extent frustrate the purpose of the seizure provisions of the statute. That purpose

its review provisions where "(1) statutes preclude judicial review, or (2) agency action is by law committed to agency discretion." Both conditions exist with respect to the probable cause determinations under Section 304 (a).

was not only to protect the consumer against products which are dangerous or branded in a respect which is harmful because materially misleading, but to do so immediately, prior to and not after the inevitable delays of litigation. Congress determined that where the Administrator had probable cause to believe that the public might be harmed or seriously misled, the potential injury to the public *pendente lite*, if distribution of the mislabeled product were allowed to continue, outweighed the harm to the purveyor of the article from the temporary detention of his property.

The sanction of multiple libels is essential to achieve the legislative purpose of arresting distribution of a dangerous product, a fraudulent product, or a materially mislabeled product "before it claims its victim".³⁹ This sanction provides the only practicable way in which dangerous, fraudulent, or seriously misbranded drugs already shipped in commerce may be removed from the market and held within the custody of law pending a determination of the alleged misbranding. Under the decision below, however, all distributors of food and drugs branded in a seriously misleading manner would have the right to challenge the Government's allegation in an injunction suit in the District of Columbia and to stay the arm of enforcement for months (or, as in this case, 11½ years) while the "probable cause" issue was in litigation.

³⁹ Quoted from H. Rep. 2755, set forth at p. 55, *supra*.

Indeed, the principal and unconcealed purpose of the instant litigation is to stay the institution of further seizure proceedings and thus permit continued distribution of the drug until after the validity of the appellee's labeling can be determined. It was precisely to avoid the evils of such delay that the Administrator was authorized to make the determination of probable cause without hearing. If the district court has the right to review the administrative decision, the beneficial effects of the expeditious procedure prescribed for administrative action would be nullified, the clear purpose of Congress would be thwarted, and great public harm could be done before shipments of contraband were reported for the institution of appropriate action.

More is involved here than the rights of the parties litigant. The public has an important stake in the determination of the jurisdictional questions. The question is not merely whether continued distribution of Nutrilite under the labeling heretofore used will be injurious or damaging to consumers, as we believe it will. The question is whether the effectiveness of the method devised by Congress for giving the public speedy protection against all nostrums believed to be harmfully misbranded shall be seriously impaired. For if appellee may seek to halt multiple seizures until a court may pass upon the correctness of the administrative determination of probable cause, so may all other distributors

whose products are thought to be so seriously misbranded as to warrant the commencement of more than one seizure proceeding. No means would then exist to protect the consumer from the injurious consequences of protracted proceedings. The damage to the public in such cases is direct and serious, not only in terms of money expended for a materially misbranded drug, but in hazards to the public health involved in self-diagnosis and experimentation with such products in the treatment of disorders requiring prompt and competent medical aid before it becomes too late.

For these reasons, the jurisdictional questions presented by this case are not mere technical matters, such as whether an issue should be tried in one forum or another. The jurisdictional questions here presented go to the heart of the effectiveness of the scheme established by Congress to protect the public health and welfare.

Adherence to the procedure set forth in the statute does not mean that a claimant such as appellee here will be denied a quick decision on the merits of his case. He has his choice of districts, and there is no reason why the libel cannot be tried as promptly as—and perhaps much more speedily than—an injunction suit in the District of Columbia. Here, the first libel against the appellee's property was filed on September 30, 1948. There is no reason to believe that the misleading character of appellee's labeling could not have been determined by one of the district courts long before this time if

appellee had not undertaken to bring the present case.

C. The District Court Lacked Jurisdiction in Equity to Review the Finding of Probable Cause

The district court also lacked jurisdiction, as a court of equity, because appellee had an adequate remedy at law.

Congress sought to establish a procedure whereby (1) when necessary for the protection of the public, distribution of seriously misbranded articles would be stopped *in limine* by seizure of the articles throughout the country, and (2) the owner of the product would not be unduly harassed by having to try a multiplicity of lawsuits.

Paragraph (b) of Section 304 contains special provisions to prevent the owner of the libeled product from having to try libel actions in different parts of the country. Where libels involving the same claimant and issues of misbranding are pending in two or more districts, they are to be consolidated for trial in "(1) any district selected by [the claimant] where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties"; or (3) in a district of reasonable proximity to the claimant's principal place of business, if so ordered by the court.

Not until April, 1949, did appellee make use of these provisions of the Act, and then only to seek consolidation in its home district (Finding 37, R. 768-769), a district not included within the districts in which a claimant is entitled as a matter

of right to obtain consolidation under the statute.⁴⁶

If appellee had obtained an order of consolidation

⁴⁶ The statutory provision permitting removal by court order to "a district of reasonable proximity to the claimant's principal place of business" (Section 304(b)) has consistently been held to mean "a district other than that of the domicile of the claimant." *United States v. 600 Units*, 60 F. Supp. 144, 145 (W. D. Mo.); *United States v. Six Dozen Bottles*, 55 F. Supp. 458, 459 (E. D. Wis.); *United States v. 26 Dozen Bottles*, 60 F. Supp. 626 (W. D. Mich.); *United States v. 23 Gross Jars . . . Enca Cream*, 86 F. Supp. 824 (N. D. Ohio); *United States v. 376 Dozen Small Size, etc., Emerson's Brand Seltzer*, (S.D. N.Y.), printed in *Kleinfeld & Dunn, Food, Drug, and Cosmetic Act, 1938-1949*, p. 1; *United States v. 15 Cartons of Sekor Reducer*, (S.D. Tex.), printed in *Kleinfeld & Dunn*, p. 12. This conclusion is supported by the legislative history of the provision. An early version of the bill expressly contemplated removal to the district in which was located the claimant's principal place of business. S. 5, 75th Cong., 1st Sess., p. 13. House draft of March 10, 1937, Dunn, p. 780. A subsequent version of the bill changed the pertinent language to: ". . . the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district in a State contiguous to the State of the claimant's principal place of business. . . ." S. 5, 75th Cong., 3d sess., House draft of April 14, 1938, p. 53, Dunn, p. 798; see H. Rep. No. 2139, 75th Cong., 3d sess., p. 4, Dunn, p. 818. The debate in the House indicated that the object of this change was to provide for trial on "what might be called neutral ground," that "the position was that the claimant is entitled to a neutral court, and it might be disadvantageous for the Government to go into the State where the claimant resided, where the influence perhaps in favor of the manufacturing concern might make it impossible for the Government to get a fair trial." 83 Cong. Rec. 7791, Dunn, p. 895. (Statement by Representative Lea, a member of the Committee). See also 83 Cong. Rec. 7784-7785, Dunn, pp. 875, 878. The final change in this language, in conference, to "a district of reasonable proximity to the claimant's principal place of business" was obviously designed to continue to exclude claimant's home district, but to allow removal to any district of reasonable proximity to claimant's principal place of business, whether that district was in the same State or not. See H. Rep. No. 2716, 75th Cong., 3d sess., pp. 22-23, Dunn, pp. 915, 998. For proof that there was a reasonable basis for not requiring the Government to proceed in a claimant's home district, see the illustration given by Judge Knox, in *A Judge Comes of Age* (Scribner's, 1941), p. 243.

in the fall of 1948 and had endeavored to obtain an early trial with as much vigor as it has pressed this case, the legality of appellee's labeling would doubtless have been long since determined, after a single trial, by jury if requested. If appellee had prevailed, its products would probably have been returned to it long before deterioration would take place. See pp. 73-74, *infra*.

1. *Multiplicity.*

It is axiomatic that equity will not grant relief where there is an adequate remedy at law. This maxim applies when relief is sought in order to avoid a multiplicity of suits. This Court has defined the standards applied when this basis for equity jurisdiction is invoked. (*Di Girolanni v. Camden Fire Ins. Assn.*, 296 U. S. 64, 70-71, quoting from *Hale v. Allinson*, 188 U. S. 56, 72-77):

"... the decision must depend largely upon the question of the reasonable convenience of the remedy, its effectiveness and *the inadequacy of the remedy at law* . . . Each case, if not brought directly within the principle of some preceding case, must, as we think, be decided upon its own merits and upon a survey of the real and substantial convenience of all parties, *the adequacy of the legal remedy*, the situations of the different parties, the points to be contested and the result which would follow if jurisdiction should be assumed or denied; . . . The single fact that a multiplicity of suits may be prevented by this assumption of juris-

diction is not in all cases enough to sustain it.
* * * [Italics supplied.]

The *Di Giovanni* case, and also *Aircraft & Diesel Equipment Corp. v. Hirsch*, 331 U.S. 752, 774-780, imply that the possibility of avoiding more than one trial at law by other procedural devices would make resort to equity unnecessary.⁴¹ Judge Parker, for the Fourth Circuit, has noted explicitly that the flexibility of modern procedures for consolidation of causes, combined with other factors, has greatly lessened the scope of the doctrine of multiplicity in the federal courts; in *Broderick v. American General Corporation*, 71 F. 2d 864, 870 (C.A. 4), he stated:

In the federal courts, however, the question is simplified by section 267 of the Judicial Code, 28 USCA § 384, which gives congressional emphasis to the rule that suits in equity shall not be sustained where a plain, adequate, and complete remedy may be had at law; by section 921 of the Revised Statutes, 28 USCA § 734, which

⁴¹ "The grounds for relief to a single plaintiff which will deprive two or more defendants of their right to a jury trial must be real and substantial and its necessity must affirmatively appear. See *Boise Artesian Hot & Cold Water Co. v. Boise City*, 213 U. S. 276, 285, 286; *Dalton Adding Machine Co. v. State Corporation Comm'n*, 236 U. S. 699, 700, 701. Respondent's bill of complaint does not show that petitioners are unwilling to abide the result of a trial of one suit as controlling both; or unwilling to try first the suit in which they would be joint plaintiffs, or that in that case the judgment would not be *res adjudicata* in a subsequent suit, or in any case would not suffice to dispose of both; or that upon appropriate application the state court would not direct the trial of the controlling case first." [296 U. S., at 72.]

authorizes a consolidation of actions where they may reasonably be consolidated; and by the Seventh Amendment to the Constitution, which requires the preservation in law actions of trial by jury. Whatever may be said in other jurisdictions as to the superior advantages of trying a number of actions at law as one suit in equity because some common question of law or fact is involved, there is little to be said in its favor in the federal courts where the presence of such common question may furnish ground for consolidation, so that even at law only one trial of the common question will be required. [Italics supplied]

The Eighth Circuit has held that the existence of a procedure for consolidation in a state court makes resort to equity inappropriate, saying (*Equitable Life Assur. Soc. v. Wert*, 102 F. 40, 15):

The plaintiff may compel the defendant to show cause in the state court why her actions should not be consolidated; and, if no such cause be shown, the several actions will be consolidated. § 20-703, Compiled Statutes of Nebraska, 1929. No reason is apparent to us why the actions brought by the defendant in the state court should not be consolidated, and, if they are consolidated, there is no practical necessity for enjoining their prosecution, since there would be then no multiplicity of suits and no unduly vexatious litigation.

That the doctrine of multiplicity may not be invoked when the cases in question can be consolidated

for trial is stated repeatedly in the exhaustive analysis in Pomeroy's treatise on *Equity Jurisprudence* (5th Ed., 1941),¹² which cites the authorities:

Since the existence or exercise of the jurisdiction, in classes third and fourth, depends on defects in the legal rules as to joinder of parties, where the legal remedy is not thus defective, but permits the joinder of the numerous parties or consolidation of the numerous suits, equity will not take jurisdiction for the purpose of awarding substantially the same relief that may be obtained at law. [1 Pomeroy, 495]

It should also be observed that if the pending actions at law are of such a nature or for such a purpose, that, according to the settled rules of the legal procedure, they may all be consolidated into one, and all tried together by an order of the court in which they or some of them are pending, then a court of equity will not interfere; since the legal remedy of the plaintiff is complete, certain, and adequate, there is no necessity for his invoking the aid of the equitable jurisdiction. [*Id.*, 506]

In cases constituting the second branch of this class, the court *may* restrain numerous simultaneous actions against the plaintiff brought by the same defendant, all involving the same questions, for the purpose of having the whole decided by one trial and decree. The court will not interfere, however, when by the rules of legal procedure, all the actions can be consolidated by order of the court of law (see § 254). [*Id.*, 611]

¹² See to the same effect, *McClintock on Equity* (1936), 314

The treatise notes that in the cases in which courts have enjoined numerous prosecutions for violation of an invalid law, "the court [had] no power to consolidate the actions." *Id.*, at 507.

These authorities, holding that the multiplicity doctrine does not permit relief in equity when cases may be consolidated at law, were concerned with ordinary legal procedures for consolidating different cases. But their reasoning obviously applies when Congress has established a special and unusual procedure for consolidating a particular class of cases even when brought in many districts throughout the United States. See *Aircraft & Diesel Equipment Corp. v. Hirsch*, 331 U. S. 752, 774-781. For the provisions of Section 304 manifest both the Congressional awareness of the problem of multiplicity with respect to seizures under the Food, Drug, and Cosmetic Act, and the manner in which Congress intended to safeguard the competing interests of the public and the distributors of the products. Congress presumably did not regard the procedure which it so carefully devised as an inadequate remedy. Since this procedure enables the claimant of the libeled product to consolidate the cases for trial, there is no room for reliance upon the doctrine of multiplicity.⁴³

⁴³ *National Remedy Co. v. Hyde*, 50 F. 2d 1066 (C.A. D.C.) does not support appellee's argument. That case was decided under the Food and Drugs Act of 1906, which did not afford a claimant the opportunity to consolidate multiple seizures, and hence no adequate remedy at law was available.

2. *Other injury.*

Appellee also claims, and the court below found (Fdg. 39, R. 769), that the seizures have caused irreparable injury by reason of (1) loss of morale among its agents and distributors, and a resulting drop in volume of sales; (2) the adverse effect of the publicity attending the seizures; and (3) loss of good will for the same reason. Such factors, which may accompany any legal proceeding in which a defendant is accused of wrongdoing, obviously do not furnish sufficient grounds for equitable intervention. *Aircraft & Diesel Equipment Corp. v. Hirsch*, 331 U. S. 752, 778-780.

The injury from the necessity for hiring counsel and defending the various libel proceedings relates to the problem of multiplicity and need not be discussed further. Appellee need do no more than file a single piece of paper in each district where a libel is pending, requesting consolidation and removal of the case for trial to one of the districts in which it is entitled to have the case tried.⁴⁴

The court below also found that appellee would suffer irreparable injury because the value of the property seized amounted to \$6,822; and because "the product so seized will be unsaleable if returned to [appellee]." (Fdg. 39, R. 769). The only evidence supporting the latter portion of this finding was that some of the vitamins in Nutrilite cap-

⁴⁴ It would even seem unnecessary to hire separate counsel in each district, since appellee could file a claim and application for consolidation in each case in its own name.

sules deteriorate with the passage of time, so that if there was "prolonged storage", such as a "year or so," there would be some "loss of potency."⁴⁵

⁴⁵ The testimony of appellants' and appellee's witnesses on this point was not in conflict. Appellee's witness Truesdail stated, in his deposition (R. 285-286):

Q. "Now, with your experience in the field of vitamins, biochemistry, and nutrition, do you have an opinion as to whether or not the lapse of time has any effect in the potency of a multiple vitamin product?"

A. "Yes, I do have an opinion on that."

Q. "What would your answer be?"

A. "Well, my answer would be that there would be a gradual loss of certain vitamin factors with prolonged storage of the product."

Q. "Would the length of time, the relative length of time, have an effect on the relative loss, that is, the longer the time, the more loss?"

A. "Yes, that would be true."

Q. "So that if a multiple vitamin product were kept without use, without being used, for a period of a year or so, you would expect to find loss of potency; is that correct?"

A. "I would expect to find some loss of potency over its original potency when it was made."

Q. "Now, do you and your laboratory have any policy with respect to the length of time that multiple vitamins should be kept on store shelves before used?"

A. "Only to the extent that we advise our clients in general to try and move their stock so that there will not be any on the shelves, if possible, any longer than six months. We feel that is a safety factor, and beyond that six months period there may be a substantial loss of certain of the more unstable vitamins."

Q. "Now, your statement to the effect that multiple vitamin products in your opinion should be moved to the consumer within six months, and I take it that means six months after compounding and manufacturing?"

A. "That is correct."

Q. "Do you apply that also to multiple vitamin products of similar nature to Nutrilite?"

A. "Well, we apply it to all vitamin products."

If appellee had proceeded promptly to consolidate the cases and request an early trial, and had been vindicated, the tablets would have been returned before their value had been impaired.⁴⁶ But, apart from that, and assuming harmful deterioration, the loss of value resulting from the fact that a product is subject to deterioration or is perishable (as must be the case for many types of food and drugs) is not a sufficient basis for departure from the statutory scheme.

D. The District Court Lacked Jurisdiction to Determine Whether Appellee's Labeling Was Misleading

The court below found that appellee's labeling was not misleading in any particular (Edg. 12(f),

Q. "Including Nutrilite?"

A. "Including Nutrilite."

Dr. Elmer M. Nelson, a witness for the Government, testified (R. 487-488):

Q. Doctor, on the basis of your experience and the supervision of your laboratory, do you have an opinion as to the deterioration rate of properly encapsulated vitamin preparations?

A. I have.

Q. And what is that opinion?

A. If vitamins are properly encapsulated there would be no measurable deterioration of vitamin A, vitamin D, riboflavin, or vitamin B-2, or of nicotinic acid, in a period of a year or even in two years.

With respect to vitamin C and vitamin B-1, there is some deterioration even in the best made preparations, and those that the Army purchased—multivitamin preparations that the Army purchased during the war—some of them showed a deterioration of the order of 5 percent per year—about 10 percent in a period of two years.

⁴⁶ It is true that if an appeal was taken the tablets would be retained for a longer time. But whether such an appeal would be taken is, of course, entirely conjectural and not sufficient foundation for a claim of irreparable injury.

R. 759-760). This was the issue which the statute commits to the courts in which the libel proceedings are to be heard.⁴⁷

Much of what has been said in the preceding sections serves to demonstrate that the court below lacked jurisdiction to try that issue. The argument in Point II(C) (pp. 65-74, *supra*) as to lack of jurisdiction as a court of equity is, of course, fully applicable to this phase of the case as well, and need not be repeated. For the right to consolidate the libel proceedings in itself provides an adequate remedy at law and makes unnecessary a determination in equity of the issues to be tried in the libel suits.

Only a few additional observations seem necessary.

The procedure established by Congress obviously contemplated that the question whether the labeling was misleading would be tried in the libel suits or one of them. The injury to the owner of the products which often results when multiple seizures are begun was to be alleviated by consolidation, not by resort to a suit for injunction in the District of Columbia.

Of some significance is the provision in Section 304(b) that "on demand of either party any issue of fact joined in any such case shall be tried by jury." The Government, as well as the claimant,

⁴⁷ The issue may also be determined, of course, in district courts in which the Government may institute other types of enforcement proceedings.

was thus given the right to insist on a jury trial. It is not difficult to think of circumstances in which the Government would consider that a jury, consisting of the type of persons to whom such representations are addressed, would be the proper tribunal for gauging their deceptive effect.

In addition, and perhaps of greatest importance, to permit the basic issue as to the deceptive character of the labeling to be decided in an injunction suit while the pending seizures were, at the command of the injunction court, held in abeyance, and while additional seizures were prohibited, would be inconsistent with the basic purpose of Section 304 to protect the public during the period of pendency of the seizure suits. The grant of a temporary injunction, as in the instant case, would reverse the policy which Congress deliberately adopted in the statute whereby, when it is believed that misrepresentation would be harmful to the public, the consumers and not the distributors were to be protected by seizure of the product in advance of trial.

III

If the District Court Had Jurisdiction to Determine Such Issues, It Should Have Found That the Facts Amply Support the Administrative Determination of Probable Cause and That Appellee's Labeling Is Misleading

If, contrary to our contention, the District Court had jurisdiction in the present case to review the validity of the administrative determinations that probable cause existed for believing that the labeling of appellee's product is materially misleading,

the scope of such review would, under settled principles governing judicial review of administrative action, be limited to an inquiry whether the determinations of probable cause, *Rochester Telephone Corp. v. United States*, 307 U. S. 125, 146; *National Labor Relations Board v. Hearst Publications*, 322 U. S. 111, 130-131; *Donaldson v. Real Magazine Co.*, 333 U. S. 178, 186; *Houston v. St. Louis Packing Co.*, 249 U.S. 479, 484-485 (no prior administrative record). We respectfully submit that the facts of record before the Administrator furnished ample support for the administrative findings of probable cause, and that the evidence adduced at the trial reinforced the correctness of the administrative determinations by proving that the labeling was in fact misleading.

Whether the labeling of appellee's product was misleading depended upon (1) the nature of the representations contained in such labeling, and (2) the truth or falsity of such representations. Each of the various officials who made the determinations of probable cause testified that his conclusion as to the character of the representations made on behalf of the product was based upon his own examination and analysis of the booklet "How to Get Well and Stay Well" (R. 315-326, 334-336; 374-378, 383, 384, 395-405, 508-510, 512). These officials testified that they had found that the booklet represented to the average reader that Nutrilite would be effective in the prevention and cure of most common and serious diseases, which would

include such ailments as high blood pressure, heart and coronary disease, pneumonia, tuberculosis, and cancer (R. 326-327, 375-378, 396, 398-400). Having found such representations in the booklet, each official relied upon the findings of fact of his medical adviser that Nutrilite would not be effective in preventing or treating most such diseases and conditions (R. 313-315, 333-334, 395, 505, 512-514). Accordingly, each official concluded that he had probable cause to believe that the labeling would be in a material respect misleading to the injury or damage of the purchaser or consumer (Deft. Ex. 12, R. 1171, 314, 315-318; Deft. Ex. 13, R. 1173, 333, 334; Deft. Ex. 15, R. 1216, 408, 395; Deft. Ex. 23, R. 1532, 518, 509, 514).

To be sure, none of the officials had before him facts showing actual physical injury or damage to any particular purchaser or consumer (R. 330, 385, 406, 507). But each based his determination on the ground that there was probable cause to believe that many consumers and purchasers, relying upon the representations made in its behalf, would use Nutrilite to treat diseases for which it was ineffective as a preventive or cure (R. 315-319, 335-336, 376-378, 395-405, 509-510). It was also testified that, in some cases the labeling of appellee's product would cause delay in obtaining competent diagnosis and treatment for serious diseases, with perhaps irreparable damage to health (R. 318, 403-404).

The evidence presented by appellee did not seriously challenge the medical findings of fact upon which the probable cause determinations were made. Indeed, there was no substantial difference between appellee's medical witnesses and appellants' as to the basic medical facts. There was agreement that Nutrilite and vitamin products generally would be useful in helping persons suffering from dietary deficiency resulting from insufficient vitamins. (R. 86, 351, 373-374.) The medical evidence presented in the District Court was also essentially in accord as to the ineffectiveness of Nutrilite in the prevention and cure of the various specific ailments referred to above. The findings of fact submitted by Dr. Butz to the administrative officials were that a product containing the ingredients of Nutrilite would not be effective in preventing or treating most common diseases, and that most common diseases do not result from dietary deficiencies (Deft. Ex. 12, 13, 15, 23; R. 1171, 314; 1173, 333; 1216, 408; 1532, 518). This was confirmed not only by the statements of three medical doctors testifying for appellants (R. 342-343, 344, 348-350, 351, 354-360, 362, 364-365, 432-434, 437, 472-478), but by appellee's medical witness, Dr. John Myer, who admitted that, with regard to such illnesses and diseases, a vitamin and mineral product like Nutrilite could not be regarded as a specific preventive or cure, and that Nutrilite was useful only as adjunctive

therapy (R. 103, 106-107, 112, 113, 131-132, 163). Nor did the findings of fact made by the District Court contradict or challenge the medical findings submitted to the administrative officials as to the usefulness of Nutrilite in the prevention and treatment of common diseases. The crux of the District Court's findings relating to the lack of factual justification for the probable cause determinations is contained in Finding 12(e) (R. 759):

(e) The three pamphlets (Pl's Exs. #1, 2 and 3), when read as a whole and fairly interpreted, without lifting statements therein out of context, do no more than represent that Nutrilite is a vitamin-mineral food supplement designed and intended to build up the bodies of human users thereof in order that it may aid nature to help the users enjoy better health through better nutrition. Said pamphlets do not represent to the minds of ordinary, reasonable and prudent persons that all of the symptoms, conditions and diseases of the human body necessarily or generally result from dietary deficiencies alone, or that all of the symptoms, conditions and diseases of the human body can be prevented, cured or treated by the use of Nutrilite, and said pamphlets do not represent, suggest, or imply that Nutrilite is a medicine or drug, or that it is efficacious or beneficial in the prevention, treatment or cure of all diseases.

These pamphlets represent the product only as a food supplement containing vitamins and minerals beneficial to building up health and

bodies and in alleviating, in some but not in all instances, symptoms resulting from vitamin and mineral deficiencies in the diet. Purchasers and consumers do not understand from these pamphlets that Nutrilite is a treatment or cure for any disease. * * *

It is clear from this passage that the court below did not believe that Nutrilite would be generally effective as a means of preventing or curing disease.

The District Court's objections to the probable cause determinations were based upon its view that the administrative officials were entirely unjustified in believing that any of the three editions of the pamphlet "How to Get Well and Stay Well" represented that Nutrilite had any such effect. Indeed, at various stages of the trial the members of the District Court strongly expressed their view that no reasonable man could read the booklet as containing any such representations (R. 115-117, 124-127, 149-150, 152, 161, 221, 242, 376, 381-382, 397, 400). A reading of the record will clearly show that this view of the District Court permeated the entire proceeding held before it.

The critical question is whether the administrative officials could reasonably have reached the opposite conclusion, that the booklets would deceive the consuming public. It becomes necessary, therefore, to analyze in detail the contents of the booklets.

The administrative officials testified that the booklet employed a familiar technique capitalizing on the average person's fear of death and illness. (R. 316, 334-335, 509). They regarded as significant the booklet attempt to make illness, malnutrition, and vitamin and mineral deficiency seem practically synonymous terms (R. 913-915), and the description of Nutrilite as a treatment for dietary deficiency disease, accompanied by the explanation that dietary deficiency disease is now being recognized in the newer branches of science as the root of the common ailments which result in premature death. (R. 323, 326, 330, 400-402). These officials knew also that, as Dr. John Myers, a witness for appellee, testified (R. 147), a person "would not be likely to buy an expensive preparation like Nutrilite" for a "simple" condition but only when "his condition got very much worse." They recognized the emphasis upon Nutrilite's "secret base" and its alleged extraordinary merit as characteristic of claims that were prevalent in the heyday of patent medicines and quack nostrums.⁴⁸ (R. 316, 334, 400).

⁴⁸ Compare *Secrecy in "Patent Medicines,"* Journal of the American Medical Association, Nov. 3, 1917, reprinted in Vol. II, *Nostrums and Quackery*, 800 (Cramp Ed. 1921), where the following statement is made:

"Practically every 'patent medicine' manufacturer leads the public to believe, either by direct statements or by implication, that his preparations possess some marvelous and esoteric powers—due either to a peculiar combination of well-known drugs or to the presence of some mysterious

The 58 page edition of the booklet involved in the first four libel proceedings unquestionably represented that Nutrilite was effective in the treatment of "severe abdominal pains" (R. 827), "splitting headaches" (R. 827), "terrific pains" in joints and hips (R. 827), "heart catches" (R. 827), "extreme fatigue" (R. 835), "sneezing and weeping" (R. 831), "nervousness" (R. 835), "tuberculosis" (R. 835), and "dizzy spells" (R. 836). These representations were in the form of testimonials given by persons who stated that they obtained relief through the use of Nutrilite. The administrative officials were entitled, on the basis of their experience, to conclude that representations in the form of such testimonials are most effective in impressing the average reader. In *United States v. John J. Fulton Co.*, 33 F.2d 506, 507, the Court of Appeals for the Ninth Circuit observed that sales pamphlets containing such testimonials have "a more persuasive appeal to

drug about which the rest of the world is ignorant—not to be found in official products or in unofficial products made by competitors. Such claims, of course, are the sheerest humbug."

No evidence was offered as to the method of preparing the "secret base" of Nutrilite or as to its final composition. Claimant's expert witness testified that the base has something that makes it more valuable than ordinary vitamins and minerals (R. 87), but on cross-examination, while stating that the base contained something "specific" and "essential", he admitted that he did not know how the base was prepared or how it fit into the curative picture. (R. 163-164). The evidence offered in support of plaintiff's case dealt not with the base and its merits, but only with the beneficial effects of vitamins and minerals.

the credulity of sufferer from these diseases than if the representations thus implied were made directly upon the authority alone of the proprietors, and for that reason they are not less, but more, obnoxious to the law.”⁴⁹

As stated, *supra*, appellee revised its 58-page booklet, first by deleting therefrom pages 37-58, and later by issuing a new 42-page ~~edition~~. Both the 36-page and the 42-page editions, while eliminating the testimonial material contained in the 58 page edition, contain numerous passages which the administrative officials correctly found to be representations on which “credulous persons”, suffering from serious diseases would rely to their possible injury or damage “despite subtle qualifying phrases”. Cf. *Reilly v. Pinkus*, 338 U. S. 269, 274. The booklet must be read in its entirety in order fully to appreciate its impact upon the average reader. The theme is simple and is developed in logical sequence, leaving the following impressions on the reader:⁵⁰ (a) Almost everyone in the

⁴⁹ The court below stated on several occasions (R. 149-152, 376, 382) that the representations in the testimonials could not be attributed to appellee and refused to permit appellants to cross-examine (R. 152) or introduce evidence (R. 382-383) for the purpose of developing their contention that the testimonials were deceptive. This was serious error.

⁵⁰ The following analysis is of the 42-page booklet (Pl. Ex. 3, R. 883-927). The 36-page booklet is almost identical with the first thirty-six pages of Pl. Ex. 3 (R. 844-882). However, on page 35, it includes a more direct statement of what is meant by “common diseases”. The statement, which was eliminated from the 42-page edition, is (R. 881):

Most of our common diseases, with the exception of germ diseases, but including some of the most painful,

United States is either ill or about to become ill, (b) almost every common illness, including those most responsible for premature death, is due to vitamin deficiencies, (c) the average American diet is deficient in certain vital food factors including both known and unknown vitamins and minerals, which are called "nutrilites" by biochemists, (d) to prevent and cure such illnesses, these food factors must be put into the body to bring it into chemical balance, for illness is merely the result of chemical imbalance in the body and health is the result of chemical balance, (e) to attain chemical balance, and thus to get well and stay well, one should use Nutrilite, which contains not only the known vitamins and minerals but also the unknown ones.

Pages 1 through 6 (R. 886-891) instill the seeds of fear. The reader is asked provocative questions (page 1):

"ARE YOU A VICTIM?"

"ARE YOU SUFFERING FROM HIDDEN HUNGER?"

"ARE YOU SLOWLY STARVING TO DEATH?"

He is asked to look around at the members of his family, his neighbors, friends and relatives, and himself. "Can you find even three or four who are

the most common causes of death from illness, those with the weirdest names, many rare diseases, and many which are considered incurable, are the result of dietary deficiencies.

The 58-page edition (Pl. Ex. 1, R. 783-843) is the 36-page edition plus 37-58. The later pages are largely comprised of testimonial material.

absolutely and completely well? Are you enjoying perfect health?"

"On the other hand * * * note how many are weak and lacking in energy, having trouble digesting their food or suffering with actual stomach pains, with decaying teeth, trouble with their hearts and other important organs, and with aches, pains and discomfort in various parts of their bodies. * * * And finally think of people you know, your age and younger, who have died in the last year, prematurely." On pages 1 and 2 (R. 886-887) the reader is asked to check himself against five criteria of good health. These are so defined as to insure that almost everyone will discover at least one respect in which he lacks good health. This section concludes: "Now—what do you think? How many of the people in your family meet these health requirements? How many of your friends measure up to these standards? Do you? Don't you think the facts point to the need for something?"

Page 10 (R. 895) continues the thesis that almost everyone suffers from a deficient diet and almost all illness results from such a deficiency; The booklet states that the "result is that almost all members of our families have bodies which are malnourished, and show evidences of the malnutrition which causes most of our common deficiency ailments." "Deficiency ailments" are defined as including "most of our current and common ail-

ments." (Page 11, R. 896). The purpose of the booklet is explained on page 10 (R. 895) as:

So the purpose of this book—and the objective of the person who lent you this book—is to bring you to the point where you will recognize the fact clearly that *your illness and the illness of your family, is, in almost every case, the result of a failure to supply your body and the bodies of the members of your family with the vital food factors.* You must realize that if you wish to preserve your health and the health of your wife or husband, have healthy, happy children, fight off the common deficiency diseases yourself, and enjoy vibrant health and an active old age, **YOU MUST PUT INTO YOUR BODY ALL THE FOOD FACTORS REQUIRED BY IT.**

This book tells you how to do this, and it supplies the answer to the enigma of modern medicine—why some people get sick so easily, and get well with such difficulty. [Italics supplied]

The term "nutrilites" in lower case is used to denote all the necessary food factors.

Pages 16-19 (R. 901-904) are devoted to a discussion of the functions of vitamins and their interrelation in preventing and treating diseases. On page 19 the "medical approach" to illness is described as consisting of combating those diseases which are caused by the entrance of foreign matter into the body "(germs and poisons, for example)". It is indicated that this "medical approach" is old-

fashioned. "The new facts are that many physical ailments and diseases are not the result of the penetration of the body by something foreign, but THE FAILURE TO PUT INTO THE BODY needed factors and materials, resulting in nutritional deficiencies." (Page 20, R. 905).

On page 20 (R. 905), it is stated that one can fight a particular disease with medicines or by "forgetting all about the symptoms and their medical names, and putting back into the body the materials the body needs for health. In this way, you are not fighting any foreign element in the body, or trying to cure anything. You are adjusting your diet so your body can restore itself to normal."

On pages 20 and 21 (R. 905-906), the reader is advised that whenever he has "an ache or pain, a weakness, wasting, unsatisfactory feeling, a lesion, a symptom, or loss of physical capacity—in short, when he is ill, there are three courses of action open

* * * The first course suggested is for the sufferer to add to his diet the essential food factors. "Then he can wait long enough to give the body a chance to rebuild, and see if that is all he needs." If the "physical ailment seems to be acute" the sufferer is advised in large capital letters to rebuild his body with *nutrilites*, and in small letters also to consult a physician. Page 21 (R. 906) states:

This procedure should be acceptable to all concerned. First, if the ailment is chronic rather than acute, no harm can come from the use of the process of physical rebuilding through food and the *nutrilites*, since the ail-

ment has likely been plaguing the person for considerable time and the sufferer is still alive. A few months devoted to rebuilding the body can hardly make things worse.

A person following this advice will be likely to avoid seeing a doctor until an ailment becomes acute. With many afflictions, such as cancer, this will be too late even if "the sufferer is still alive." See R. 318.

Pages 23-40 (R. 908-925) are concerned with a discussion of the enemies of health, namely, depleted soil, improper cooking, processing, and storage and shipping delays which deprive the public of needed food elements—all designed to show that most persons are not properly nourished—and with the presentation of the apparently simple solution to this serious problem.

On page 28 (R. 913) appears this statement:

* * * the result of diet deficiencies may show itself as one of the common or not so common deficiency diseases, including those most responsible for death in our 40's and 50's, whereas we should live in good health and vigor, and with full possession of our faculties, to the age of 90 or 100.

A ray of hope is offered on the same page:

Chemical and biological sciences have established the fact of the chemical nature of the life process and that living things of all kinds must be in chemical balance to be normal. Most of the ills and diseases of human beings are un-

necessary—they are the result of chemical starvation of our bodies for substances vitally necessary to life.

In short, the impression is given that “adverse physical conditions” (p. 28, R. 913), “most responsible for death in our 40’s and 50’s,” no matter what their medical names, result from failure to obtain the nutrilites and thus to keep the body in “chemical balance.” “When your body gets out of chemical balance, you are ill. When you get into chemical balance and stay there, you are well.” (Page 30, R. 915.)

On page 33, after stating falsely (see page 92, *infra*) that a recent study shows that “only one in a thousand is not suffering from deficiency—from malnutrition”, the booklet declares “either we are now experiencing some deficiency disease, or we are ready to come down with one.” (R. 918)

On pages 39 and 40 the word “Nutralite” in upper case is used for the first time. Here, at last, the solution is presented; all the essential food factors—even those that are unknown—are found in Nutralite Food Supplement (R. 925):—

The sufferer with dietary deficiencies and deficiency ailments has the problem of getting into his body all the basic food factors which either were never in his food to start with or which have been partially removed in some way. If you are such a sufferer, how can these basic food factors be added to your food? We believe that NUTRILITE Food Supplement is at least one answer.

The man, woman or child who is reasonably well, and who wishes to stay that way and if possible improve, has also the problem of keeping his body supplied with all the vital food factors. If you are in this group you too have a problem, in this civilized age of devitalized and imitation food. And here again, you can turn to—NUTRILITE Food Supplement.

Finally, the fourth edition of the booklet (but not the earlier ones), on its final page (page 42, R. 927), contains warnings that a food supplement only improves "your nutritional status", that "if there is any evidence that a doctor should be consulted, you should do so" and that "you may have other conditions that require the services of a physician, in which event you should consult a doctor immediately. It is a sound health rule to see your dentist twice a year and to have a regular periodic check-up by your physician."⁵¹ This could hardly be expected to counteract all which preceded it.

The evidence adduced at the trial also proved that several material representations in the booklets were clearly false. Documentary evidence offered by appellants to show such falsity was not contradicted by appellee. Five specific instances may be cited:

(1) On pages 3 and 4 of the booklet is a fragmentary and incomplete quotation from a New York Times article for June 29, 1945, which in its

⁵¹ The 58 and 36-page editions recommend that a physician be consulted only if the condition is acute (R. 805-806, 866-867).

context attributes to vitamin and mineral deficiencies the high rejection rate for women applying for the W.A.C. (R. 888-889). Defendants' Exhibit 4, a photostat of the article, shows the specific causes of rejection, which do not include vitamin and mineral deficiencies. (R. 1059, 234).

(2) On Page 4 of the booklet appears a statement that a survey by a large eastern college showed that only 2 out of 2511 persons studied in Pennsylvania were receiving the vitamins, minerals, and proteins they needed (R. 889). Defendants' Exhibit 17 is a copy of the official report of that survey conducted by the Pennsylvania State College (R. 1225, 456-457). It does not support the claim in the booklet. (R. 457-458, 1247).⁵²

(3) On Page 6 of the booklet appears the statement that 32% of draftees in World War II were rejected and that 52½% had some disability (R. 891). These statements are presented in a context which was intended to and does, in fact, force the reader to conclude that these rejections and disabilities are the result of vitamin and mineral deficiencies. Defendants' Exhibits 5, 19,

⁵² The report states that "only two boys * * * were uniformly high in all of the tests given to them" (R. 1247). Examination of the report as a whole (R. 1225-1248) shows that the quoted passage does not by any means justify the appellee's assertion that all of the other persons covered by the survey "lacked the proper nutrition" and were "not receiving the vitamins, minerals and proteins they needed!" (R. 889). Appellee apparently relied upon an inaccurate newspaper summary of the report (R. 1249).

and 20 are copies of official selective service statistics on causes for rejections during World War II; vitamin and mineral deficiencies accounted for a very negligible percentage of such rejections. (R. 1061, 1250, 1391, 465, 1063, 1068-1074, 1086-1099, particularly 1098, 1264-1274, 1404-1411.)

(4) Pages 7, 8 and 9 of the booklet contain statements that Carl Rehnborg, the discoverer of Nutrilite, "majored in biochemistry in an eastern university"; that he "specialized in the chemistry of foods"; that he took part in "early vitamin research experiments"; and that he "returned to the United States in 1927" and "began a six year period of intensive study and experimentation." (R. 892-894). Defendants' Exhibit 24, a stipulation concerning the education and background of Carl Rehnborg, proves conclusively the falsity of these statements (R. 1542, 520).

(5) Page 11 of the booklet explains that common deficiency ailments include most of our current and common ailments (R. 896). Page 28 claims that "common deficiency diseases" include the diseases "most responsible for death in our 40's and 50's." (R. 913). Defendants' Exhibit 25 gives the leading causes of death from 1945 to 1947 as diseases of the heart, cancer, tuberculosis, pneumonia, nephritis, diabetes, and intracranial lesions of vascular origin. (Def't. Ex. 25, R. 1543-1545, 529. Vitamin deficiency diseases accounted for only 973 out of 1,445,370 deaths reported in 1947. (R. 1551).

Exhibit 26, which would have shown that the same was true for deaths of persons in the 40's and 50's, was excluded by the court below (R: 529-530).⁵³

This summary and analysis of the representations contained in the booklets, in the light of the conceded medical facts as to the inability of Nutrilite to cure or prevent most common diseases, demonstrate that the booklets were designed to give readers a false impression that Nutrilite would prevent or cure all but acute ailments, and that almost everyone needed it in order to avoid a dietary deficiency. There was thus ample basis for the determinations made by the administrative officials that they had probable cause to believe that the labeling was materially misleading. The officials were not required to find that every statement was literally false. The statutory standard which they applied, and properly so, in making their determinations, has been defined by this Court in *United States v. 95 Barrels * * * Vinegar*, 265 U. S. 438, 442-443, as follows:

The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or de-

⁵³ Such official statistics would seem in any event to be judicially noticeable. They show that the proportion of deaths in the 40's and 50's resulting from vitamin deficiency diseases was insignificant. See "Vital Statistics—Special Reports, National Summaries—Death and Death Rates for Selected Causes by Age, Race, and Sex, United States, 1947, Volume 31, Number 11."

ceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.

This principle was reaffirmed by this Court in *Donaldson v. Read Magazine*, 333 U. S. 178, 188-189, in which the Court stated:

Advertisements as a whole may be completely misleading although every sentence separately considered is literally true. This may be because things are omitted that should be said, or because advertisements are composed or purposefully printed in such way as to mislead. * * * Questions of fraud may be determined in the light of the effect advertisements would most probably produce on ordinary minds. * * * People have a right to assume that fraudulent advertising traps will not be laid to ensnare them. "Laws are made to protect the trusting as well as the suspicious." *Federal Trade Comm'n v. Standard Education Society*, 302 U. S. 112, 116.

If the booklets be tested in the light of these standards, there can be no question that they are materially misleading. And since the result might be to induce consumers to use Nutrilite for symp-

toms of common diseases as to which delay in effective treatment might be dangerous, if not fatal; it is clear that the misbranding would be injurious to consumers.

—With respect to the lawfulness of the finding of probable cause—if it is reviewable at all—the only question is whether the administrative finding is one which could be made by a reasonable man, not whether the court would reach the same decision. We submit that the evidence more than satisfies this burden. Indeed, the record demonstrates as a matter of fact that the booklets were unquestionably misleading. Consequently, even if this Court should conclude that the ultimate issue as to the character of the labeling is before it, i. e., whether the “labeling is false or misleading in any particular”,⁵⁴ we submit that it should hold that the labeling is misleading and that the conclusion of the court below to the contrary is clearly erroneous.

Appellee's good faith, if any, is irrelevant. One further matter deserves discussion, since it apparently misled the court below and influenced both its decision and its rulings on evidence to a substantial degree. The court below concluded that appellee acted in good faith in preparing and using the pamphlet (Fdg. 12(f), R. 759-760). Even if

⁵⁴ Federal Food, Drug and Cosmetic Act, Sections 403(a), 502(a), 21 U.S.C. Sec. 343(a), 352(a). Only in reference to the preliminary finding of probable cause does the statute impose a more stringent standard and require that misbranding be “in a material respect misleading to the injury or damage of the purchaser or consumer” (Section 304(a), 21 U.S.C. 334(a)).

true, this was irrelevant. As the passage quoted at page 56, n. 32, *supra*, from the House Committee Report demonstrates, Congress deliberately eliminated intent as an element for this type of offense. This Court squarely so held in *United States v. Dotterweich*, 320 U. S. 277, 281, saying:

Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States v. Balint*, 258 U. S. 250. And so it is clear that shipments like those now in issue are “punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares . . .” *United States v. Johnson*, 221 U. S. 488, 497-98.

Apart from this, and despite the holding of the court below, we submit that appellee’s good faith is highly questionable. It is true that whenever apprised of the fact that the Food and Drug Administration was investigating its practices, appellee consulted counsel, sought to confer with officials of the Administration, and toned down the exaggerations contained in its booklets. But this does not manifest good faith, but merely an attempt to

keep out of trouble. The original booklet, upon which the criminal prosecution was based (Def't. Ex. 7, R. 1104, 298), represented much more affirmatively than the later versions that Nutrilite would prevent and cure serious diseases. See pp. 6-7, *supra*. It seems highly unlikely that these representations could have been made in good faith. Appellee's repeated modifications of the booklet, without ever changing the impression which it was designed to make on the average consumer, shows merely that appellee was seeking to avoid prosecution by the Government, not to be honest and above-board in its dealings with the public.

IV

Reversible Error Was Committed by the Court Below in Limiting Cross-Examination and in Ruling on the Admission and Exclusion of Evidence and on Appellee's Rights to Pre-Trial Discovery.

We have argued that the District Court lacked jurisdiction to review the findings of probable cause or to determine for itself whether appellee's labeling was misleading, and also that in any event the testimony of record demonstrates that the administrative finding was adequately supported and that the labeling was misleading. Only if the Court should decide all these contentions adversely to the Government will it be necessary to deal with the errors committed by the District Court in the course of the trial.

Some of these errors have a significant bearing upon the decision of the factual questions for sev-

eral reasons. Thus, to the extent that cross-examination was improperly restricted and evidence offered by appellants excluded, the record considered by the court below was deficient. This Court cannot know what would have appeared in the record if cross-examination had not been limited. The improper restriction of cross-examination is a recognized ground for reversal. *E.g., Reilly v. Pinkus*, 338 U. S. 269.

1. *Curtailment of Cross-Examination.* The trial court unreasonably restricted the cross-examination of Casselberry and Dr. John Myers, the principal witnesses for the Company. They were allowed on direct examination to express broad opinions as to what the booklets convey to the public, and to say, without discussing any specific parts of the labeling, that there are no false or misleading claims made in the booklets (R. 51-53, 85-86). This type of direct examination enabled the witnesses in very brief testimony to vouch for the truth of all statements made in the 136 pages of printed matter that comprised the three editions of "How to Get Well and Stay Well."

Both in order to determine the meaning of the representations in the booklets and to test the veracity and candor of the witnesses' testimony that the booklets were in no way misleading, appellants sought to cross-examine Dr. Myers and Casselberry at length by confronting them with a great many passages from the booklets and eliciting the wit-

nesses' understanding of them. It is not at all inconceivable that if forced by vigorous and persistent cross-examination to justify a great many of the statements in the booklets, such as those quoted in the preceding Point, their testimony would have been discredited. Only through such an examination, which the court below did permit, was Dr. Myers compelled to express his understanding of such phrases used in the booklets as "common illnesses" (R. 94-95), "common diseases" (R. 96-122) and the like, and to concede that in all of the "common diseases" he had mentioned, vitamin pills alone would not help or cure (R. 112, 127), that Nutrilite would not cure any of the common diseases (R. 106-107), that he was unable to name any common dietary deficiency diseases that cause death in the 40's and 50's (R. 133-139), that if common symptoms were treated with Nutrilite it would be useless unless, as sometimes may happen, those symptoms in the particular case were due to vitamin deficiencies (R. 145-148), and that he treats no specific disease with Nutrilite (R. 163).

The court refused to allow further cross-examination of Dr. Myers with respect to the accuracy of the statements in the booklets on the ground that further questioning would be repetitious and that the cross-examination had already taken much too long (R. 169, 173, 181-183). But the subject to be explored was a difficult and important one—and the right to explore it had not been lost by the prolonged questioning necessary to get truthful

and adequate answers on another subject. The court also refused (R. 151-152) to permit cross-examination as to the testimonials found in the 58-page booklet (Pl. Ex. 1, R. 783, 272), because of its erroneous view (see pp. 83-84, *supra*) that false impressions conveyed in testimonials quoted by appellee could not be attributed to appellee.

The cross-examination of Casselberry was similarly curtailed. Although Casselberry had testified on direct-examination "positively that they are not false and misleading" (R. 231),⁵⁵ Judge Clark ruled that his testimony could not be challenged through cross-examination upon identified statements in the booklets because it was up to appellants to disprove Casselberry's statements as a part of their own affirmative case through their own witnesses but not through cross-examination, because the examination was argumentative, and because the booklets as written documents spoke for themselves (R. 231-233).⁵⁶ The forbidden cross-exami-

⁵⁵ The quotation is from Judge Clark's characterization of Casselberry's testimony.

⁵⁶ In order that the record might indicate the scope of the cross-examination contemplated, counsel for appellants stated his intention to go through the entire booklet in an attempt to have the witness explain the purposes of the many statements therein regarding diseases (R. 232). The court admonished counsel to desist and stated: "The Court will sustain objections to any such questions. You can embody them in an offer of proof if you want to" (R. 232). The court refused to allow counsel to identify for the record the passages in the booklet as to which he wished to inquire, stating: "The Court is not going to waste time letting you go through the booklet. You can make your offer of proof in writing and the Court will consider it." (R. 233). But when the written "offer of proof" was presented, the court rejected it on the

nation might well have undermined the direct testimony of appellee's two main witnesses, as well as basic claims as to the meaning of the booklets. Unless this Court is of the view that the booklets themselves so clearly prove their own innocence that no evidence at all with respect to their meaning and purpose was admissible, this was serious error, for it went to the heart of the case. And in any event the subject should not have been open to appellee's counsel on direct examination but closed to appellants' on cross-examination.

The right to full and complete cross-examination of adverse witnesses is essential to a fair trial. *Alford v. United States*, 282 U. S. 687; *District of Columbia v. Clawans*, 300 U. S. 617; *Reilly v. Pinkus*, 338 U. S. 269. We respectfully submit that the trial court abused its discretion in limiting and cutting off proper cross-examination.

2. *Objections at Trial to Questions Propounded in an Oral Deposition.* The court ruled, over appellants' objection, that the appellants were precluded from objecting to testimony contained in the deposition of Lee Myers because objection had not been saved at the time the deposition was taken (R. 252, 254). This was directly contrary to Rules 26(e) and 32(c)(1) of the Rules of Civil Procedure.

ground that the questions had not been asked orally and passed upon by the court (R. 520-528). And though Casselberry was then present, the appellants' request that he be recalled so that the questions in the offer of proof might be asked orally, and a separate ruling obtained on each question, was denied (R. 527-528).

Rule 26(e) provides that objection may be made at the trial to the receipt in evidence of any deposition or part thereof which would require its exclusion if the witness were then present and testifying. And Rule 32(c) (1) provides:

Objections to the competency of a witness or to the competency, relevancy, or materiality of testimony are not waived by failure to make them before or during the taking of the deposition; unless the ground of objection is one which might have been obviated or removed if presented at that time.

The court, without suggesting that it was acting under the last clause quoted, ruled that appellants' objections at the trial were too late. Cf. *Laird v. United Shipyards* (S.D. N.Y. 1941) 1 F.R.D. 772.

3. *Exclusion of Official Statistics Showing Causes of Death.* The trial court excluded Defendants' Exhibit 26, an official publication entitled "Vital Statistics—Special Reports, National Summaries—Death and Death Rates for Selected Causes by Age, Race, and Sex: United States 1947, Volume 31, Number 11" (R. 529-530). The court had previously admitted a similar report (Def't. Ex. 25, R. 1543, 529) which differed mainly in that it did not show causes of death by age groups, but, according to Judge Clark, this was admitted "in the interests of saving time" and "because it has no probative effect one way or the other" (R. 528-529). Exhibit 26 was relevant to the claims made

in "How to Get Well and Stay Well" that diet deficiencies were causes of premature death, and that common-deficiency diseases are among the diseases "most responsible for death in our 40's and 50's." (R. 913.)

The exhibit was excluded because the court assumed without reading it that it was "a self-serving-declaration" (R. 529), in that it was a publication of the National Office of Vital Statistics, Public Health Service, a constituent of the Federal Security Agency. But there is no circumstance that makes the data untrustworthy in this action. Certainly there is no reason to believe that the pendency of the present case gave the Federal Security Administrator cause to direct the publication of untrue vital statistics.

In any event it has long been settled that official public records of this type are admissible. Cf. *Evanston v. Gunn*, 99 U. S. 660, 666. These statistics are required by law to be compiled and published. 13 U.S.C. 101 and 42 U.S.C. 245. It obviously was impossible for the appellants to prove the causes of the 1,445,370 deaths reported in the publication by any more satisfactory means.

4. *Erroneous Admission and Exclusion of Medical Writings.* Appellants offered in evidence a medical publication entitled "Deficiency Diseases in the Cincinnati Hospital; a Ten Year Study" (R. 425), through its author, Dr. Marion A. Blankenhorn, an outstanding medical expert in the

field of nutrition (R. 422-425). This article was highly relevant as a means of showing that dietary deficiency diseases, such as were emphasized in appellee's booklets, are rare to non-existent at the present time. The article was excluded as hearsay (R. 425-426), although the author was on the witness stand and subject to cross-examination (R. 425). It is well established that a learned treatise is admissible in evidence if its author is present and subject to cross examination. Wigmore, *Evidence*, 3rd Ed., § 1690 and cases cited; *La Count v. General Asbestos and Rubber Co.*, 184 S. C. 232, 241-242, 192 S. E. 262, 266-267; *Brown v. Interstate Business Men's Assoc.*, 57 N. D. 941, 943-944, 224 N. W. 894, 895; *Ruud v. Hendrickson*, 176 Minn. 138, 222 N. W. 904. This was error.

The court admitted in evidence, however, a compilation of excerpts from medical publications, when offered through appellee's witness Casselberry, who was not a physician. This was admitted to show appellee's good faith, a factor which Congress clearly made irrelevant in the Food, Drug, and Cosmetic Act (R. 50, but see R. 219). See pp. 96-98 *supra*. Such excerpts, so introduced, clearly were inadmissible to prove the truth of the facts asserted. *United States v. One Device* * * * *Colonic Irrigator*, 160 F. 2d 194 (C. A. 10); *Union Pacific Railway Co. v. Yates*, 79 Fed. 584 (C. A. 8).

5. *Inconsistent Rulings as to Testimony of the Effect of the Booklets upon the Public.* The court

permitted two of appellee's witnesses, Attorney Myers and Dr. Myers to express opinions as to the impression the labeling would leave with the public (R. 85, 258-259). Even the doctor obviously had no special expertise as to the impression which the booklets would make on minds not medically trained. But the court held Mr. Crawford, Associate Commissioner of Food and Drugs, and an expert of many years' experience in food and drug regulation for the protection of consumers, incompetent to testify regarding such impression (R. 382-383).

6. *Inconsistent Rulings as to Testimony on Medical Facts.* The court below permitted Casselberry and Attorney Myers, both of whom were without qualifications as experts in the field of nutritional disease, to offer expert testimony as to medical facts (R. 32-35, 37, 50, 258). This also was error. Recognizing the rule that a determination of the competency of an expert lies within the sound discretion of the trial court (*Clarke v. Hot Springs Elec. Light & Power Co.*, 55 F. 2d 612 (C. A. 10)), certiorari denied 287 U. S. 619, we believe it a clear abuse of discretion to accept expert medical opinion testimony from witnesses who qualify only as attorney and psychologist.⁵⁷ Only those persons with

⁵⁷ Casselberry holds B.A., M.A., and Ph. D. degrees. His experience has been that of credit manager, real estate salesman, teacher, research worker for delinquent boys, vocational counselor, and consulting psychologist. His doctoral thesis was "Symptomatic Factors in Delinquency" (R. 32, 183-186).

training and experience in medicine or nutrition are competent to give expert opinion testimony as to the medical facts within those specialized fields. Cf. *Spring Co. v. Edgar*, 99 U. S. 645; *Aetna Life Ins. Co. v. Kelley*, 70 F. 2d 589, 592 (C. A. 8); and *United States v. McCreary*, 105 F. 2d 297, 299 (C. A. 9).

The court refused, however, to allow Dr. Elmer M. Nelson, Chief of the Nutrition Division, Food and Drug Administration, who was not a medical doctor but was an expert in the field of nutrition, to make comparisons between the daily dosage of Nutrilite and the minimum daily requirements for the several vitamins and minerals contained therein as established pursuant to law by the Federal Security Administrator (R. 488-490). This testimony was excluded both because Dr. Nelson was not a physician, and because "The Food and Drug Administration is on trial in this case, and it doesn't seem that their standards ought to be taken as the standards of scientific research" (*ibid.*).

Plaintiff's Exhibit 7 (R. ¹⁸⁰⁰~~100~~ 51), which Casselberry (R. 51) and Attorney Myers (R. 249) said was a part of the material relied upon in the revision of the labeling, is a copy of a final order promulgated by the Federal Security Administrator establishing labeling statements required to be made on food for special dietary uses. 21 C. F. R. Section 125. Finding 12 (a) (R. 758) is based in part upon this administrative order. But

appellants were not allowed to show the relationship between Nutrilite and the standards set forth in the regulation, and thus to rebut the appellee's claim of reliance upon the regulation.

7. *Error in Allowing Discovery of Administrative Records and Interrogation of Administrative Officials.* The court erred in denying appellants' motion to quash subpoenas *duces tecum* served in connection with the oral interrogation of the Federal Security Agency defendants.⁵⁸

The motion to quash raised two basic points: whether the administrative officials properly could be interrogated as to the details of their decisional processes, and whether the appellee could require the appellants to deliver to it all of the records of the Food and Drug Administration relating to the Company, its predecessors, and the manufacturer of Nutrilite without showing good cause under Rule 34.⁵⁹ (R. 746).

⁵⁸ This question, though important, could not have been presented to this Court at any earlier time.

⁵⁹ None of the reasons advanced by appellees or the court below constituted "good cause". The hearing on the motion was held on April 19, 1949, before Judge Clark. Counsel for appellee justified the all-encompassing coverage of the subpoena by insisting that he did not know what was contained in the Government's files (R. 672-675); that he "would like to know so we can meet it at the trial" (R. 675); and that "it might give me a lot of leads to the oppressive things they have done, why they have done them, and who is back of them" (R. 676). Judge Clark said that this case "is outside of the general rule" (R. 673); that though depositions of administrative officials were pending, "they . . . [are] entitled to have the basis of what the oral depositions would probably be" (R. 673); and that they "cannot know . . . what they want to find" (R. 673). He concluded that ap-

United States v. Morgan, 313 U. S. 409, 422, holds that it is not the judicial function to probe the mental processes of the administrative officials. Cf. *De Cambra v. Rogers*, 189 U. S. 119, 122.

And *Hickman v. Taylor*, 329 U. S. 495, holds that discovery has necessary boundaries, which under Rule 34 is a showing of good cause. See *Alltmont v. United States*, 177 F. 2d 971 (C. A. 3) and *North v. Lehigh Valley Transit Co.*, 13 Fed. Rules Serv. 26 b. 211, Case 5 (E. D. Pa.). The trial court completely disregarded the rule in denying the motion to quash.

These are the most prominent of the trial errors which we believe were committed in the course of the proceeding below. Only a reading of the entire record, however, can give the court a really accurate impression of what transpired.

It may be that the Court would not regard any one of these errors as in itself sufficiently important to require reversal of the judgment below. In their cumulative effect, however, they seriously prejudiced the defense of this case in the trial court.

appellee had a "right of deposition to discover the position of the government and to determine whether the reports on which the government has operated is relevant or not . . ." (R. 678), and that appellee is "entitled to look at all the documents in the discovery process . . ." (R. 679).

CONCLUSION

For all of the above reasons the judgment below should be reversed, with directions to dismiss the complaint.

Respectfully submitted,

PHILIP B. PERLMAN,

Solicitor General.

JAMES M. MCINERNEY,

Assistant Attorney General.

ROBERT L. STERN,

PHILIP ELMAN,

*Special Assistants to the
Attorney General.*

VINCENT A. KLEINFELD,

Attorney, Department of Justice.

WILLIAM W. GOODRICH,

SELMA M. LEVINE,

ALVIN L. GOTTLIEB,

Attorneys, Federal Security Agency.

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